



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,046	09/24/2003	Frank Hardt	RO0233US.CON (#90568)	5022
28672 7590 02/17/2009 D. PETER HOCHBERG CO. L.P.A. 1940 EAST 6TH STREET CLEVELAND, OH 44114			EXAMINER DESAI, ANISH P	
			ART UNIT 1794	PAPER NUMBER
			MAIL DATE 02/17/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte FRANK HARDT
and PAUL GENICH

Appeal 2008-1248
Application 10/670,046
Technology Center 1700

Decided:¹ February 13, 2009

Before BRADLEY R. GARRIS, JEFFREY T. SMITH, and
LINDA M. GAUDETTE, *Administrative Patent Judges*.

GAUDETTE, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is an appeal from the final rejection of claims 1-8, the only claims pending in the Application. (Appeal Brief filed December 29, 2006. (“App. Br.”) 4.) We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

The “invention pertains to medicinal products, i.e., to products for topical administration of certain pharmaceutically active ingredients to the human skin.” (Reply Brief filed July 5, 2007 (“Reply Br.”) 10.) Appellants’ Specification states, more specifically, that an “object of the invention is to provide adhesive die-cut articles in the form of plasters which contain active ingredient.” (Spec. [0007].) According to the Specification, “[f]orms of medication to be applied to the skin and having the appearance of traditional plasters are known, containing medicaments which are to be discharged to the skin and, for example, are known as corn plasters.” (Spec. [0005].)

Independent claim 1 is illustrative of the invention and is reproduced below:

1. An adhesive die-cut article having an external contour comprising an adhesive layer with an internal cut-out having a contour, wherein the external contour of the adhesive die-cut article has no common point with the contour of the internal cut-out, a matrix layer having an internal cut-out which is congruent with the internal cut-out in the adhesive layer, said matrix layer being a compacted material, and a covering film covering the composite of matrix layer, adhesive layer, and internal cut-out, wherein the internal cut-out is filled with filler material containing a pharmaceutical active ingredient selected from the group consisting of salicylic acid, lactic acid, 5-fluoruracil, capsaicin, acetyl-salicylic acid, and nonoic acid vanillyl amide.

The Examiner relies on the following prior art reference to show unpatentability (Examiner's Answer mailed May 1, 2007 ("Ans.") 3) :

Kreckel	5,244,677	Sep. 14, 1993
---------	-----------	---------------

Appellants request review of the following grounds of rejection (App. Br. 8):

1. claims 1-8 under 35 U.S.C. § 112, second paragraph, as indefinite;
2. claims 1-8 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement; and
3. claims 1-8 under 35 U.S.C. § 103(a) as unpatentable over Kreckel.

First and Second Grounds of Rejection: claims 1-8 under 35 U.S.C. § 112, second paragraph, as indefinite, and under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement

ISSUES

The issues presented for our review with respect to the first and second grounds of rejection are:

(1) Have Appellants shown that the Examiner reversibly erred in concluding that the claim term "compacted material" renders claim 1, as well as dependent claims 2-8, indefinite?

(2) Have Appellants shown that the Examiner reversibly erred in determining that the claims are not enabled because the Specification fails to teach which materials constitute suitable "compacted material[s]"?

We answer both of these questions in the affirmative for the reasons discussed below.

FINDINGS OF FACT (“FF”)

1. Paragraph [0031] of Appellants’ Specification reads:

Natural and synthetic polymers are likewise preferably considered for the matrix layer 6, such as polyacrylates, polyethylenes, polypropylenes, polybutylenes, polyurethanes, poly-1-butenes, polyisobutene, rubbers, silicon rubbers, cellulose, chemical pulp, paper, cotton, acetylcellulose, celluloid, viscose, polyacrylonitrile, polyvinyl alcohol, polyvinyl acetate, polyvinyl ether, ethylene-vinyl acetate copolymers (EVA) and the like. These materials, and consequently the matrix layer 6, are non-adhesive. They may be present as a compacted material, foam, fabric, porous sheet, nonwoven fabric, etc.
2. Original claim 9, now canceled, appears below:

9. Adhesive die-cut article according to claim 1, wherein the matrix layer is a compacted material selected from the group consisting of a foam, a fabric, a porous-sheet or a non-woven fabric.
3. The Examiner contends that the appealed claims are indefinite because the claim 1 phrase “the matrix layer being a compacted material” is “vague, indefinite and confusing since the specification contains no teachings (with the cancellation of former claim 9) as to just what constitutes a ‘compacted material’.” (Ans. 3.) The Examiner notes that Specification paragraph [0031] “recites only that the matrix material can be a ‘compacted material, foam, fabric, porous sheet, nonwoven fabric, etc.’” while “cancelled claim 9 taught that a compacted material suitable for use could, however, be any one of the last four embodiments.” (Ans. 3.)

4. The Examiner further contends that the appealed claims are not enabled because “the specification in its present form is believed to shed no light as to just what embodiments constitute a suitable ‘compacted material’.” (Ans. 4.) The Examiner maintains that Specification paragraph [0031] “teaches only the equivalence of a ‘compacted material’ with any of the four embodiments which were also set forth in the Markush grouping of cancelled claim 9.” (Ans. 4.)
5. Appellants disagree with the Examiner’s assertion that one of ordinary skill in the art would have understood the Specification as teaching that “foam, fabric, porous sheet, nonwoven fabric, etc.” (Spec. [0031]) are *equivalents* of compacted material. (App. Br. 14.) Rather, Appellants maintain that the ordinary artisan would have understood that these materials are *alternatives* to compacted material, rather than examples thereof. (Applicant Response to Order (“Response”), filed October 17, 2008, 3 (4).) Appellants explain that the listed materials may be present as non-compact materials (Reply Br. 9), or “may be selected to become a compacted material . . . (i.e., the compacted material may be based on a foam, fabric, porous sheet or non-woven fabric)” (Reply Br. 9 (referencing original claim 9)). (*See also*, Response, paragraph bridging 3-4.)
6. Appellants maintain that “one skilled in the art would readily be aware what constitutes a compacted material.” (Reply Br. 9.) In support of this argument, Appellants point out that the USPTO Patent Classification System “defines what constitutes a ‘compacted fiber article’ in Class 28, Subclass 121,” and “defines ‘compacting’ as

- ‘subjecting the contents material to forces which crowd portions of the contents into a more confined space or which contract or elongate the contents without breaking” in Class 53, Subclass 436. (App. Br. 12 (citing Exhibits C & D of the Evidence Appendix to the Brief).)
- Appellants further identify Class 100, Subclass 35+, as related to methods and apparatus for subjecting material to compressive force and compacting it to a smaller volume. (App. Br. 12.)
7. The Examiner’s discussion of Appellants’ evidence (Appeal Br., Evidence Appendix) is limited to an acknowledgement that “‘compacted materials’ are known in the literature” (Ans. 4). The Examiner maintains that the term “compacted materials” includes many other materials which are clearly non-operative. (Ans. 4.)
 8. According to Appellants, “one skilled in the art would clearly recognize that the compacted material for the claimed die-cut article would be limited to those compacted materials which are pharmaceutically acceptable materials and which are approved for their reliability and security in pharmaceutical use.” (Reply Br. 10.)
 9. The Merriam-Webster Online Dictionary defines “compact” as “to knit or draw together: COMBINE . . . to press together: COMPRESS . . . *intransitive senses*: to become compacted.” (App. Br., Exhibit B; *see also*, App. Br., paragraph bridging 11-12.)

PRINCIPLES OF LAW

A claim is considered indefinite if it does not reasonably apprise those skilled in the art of its scope. *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1217 (Fed. Cir. 1991); *In re Venezia*, 530 F.2d 956, 958-59 (CCPA 1976). “The definiteness inquiry focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the specification.” *BJ Servs. Co. v. Halliburton Energy Servs.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003) (quoting *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.2d 684, 692 (Fed. Cir. 2001)). “[T]he definiteness of the language employed must be analyzed—not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.” *In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971). *Cf. KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (2007) (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”)

“A determination of claim indefiniteness is a legal conclusion that is drawn from the court’s performance of its duty as the construer of patent claims.” *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008) (quoting *Personalized Media Commc’ns, LLC v. Int’l Trade Comm’n*, 161 F.3d 696, 705 (Fed. Cir. 1998)).

During prosecution of a patent application, “[t]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” Those sources include “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.”

Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (internal citation omitted).

“[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). “[E]nablement is a question of law.” *BJ Servs. Co.*, 338 F.3d at 1371-72.

ANALYSIS

Appellants have persuasively argued that one of ordinary skill in the art at the time of the invention would have been familiar with the types of materials encompassed by the claim term “compacted material” and the methods necessary to produce such materials. The Examiner has not presented detailed arguments or evidence to rebut Appellants’ evidence as to the level of knowledge and skill of the ordinary artisan. Rather, the evidence supports Appellants’ contention that one of ordinary skill in the art would have been familiar with suitable types of compacted materials and

appropriate techniques for the manufacture thereof², and that one of ordinary skill would have understood that “foam, fabric, porous sheet, nonwoven fabric, etc.” (Spec. [0031]) may be present as non-compact materials or may be selected to become a compacted material. Thus, the Examiner has not persuaded us that the choice of an appropriate compacted material for use in Appellants’ claimed matrix layer would require undue experimentation. (See Ans. 5-6; Reply Br. 10.)

Accordingly, we determine that the Examiner has not met the initial burden to establish a prima facie case of unpatentability under 35 U.S.C. § 112, first and second paragraphs.

² We note that the following patents evidence use of the term “compacted material” at the time of Appellants’ invention in related fields of endeavor:

U.S. 5,497,789, issued to Zook on March 12, 1996, discloses a foot protector, such as a corn pad (col. 3, ll. 46-47) comprising a viscoelastic gel which is “capable of delivering a pharmacologically active substance to [a] foot lesion” (Abstract.) Zook notes that prior art materials include foam rubber and other compressible materials. (Col. 8, ll. 50-51.) Zook explains that when pressure is applied to these prior art materials, they “decrease in volume and increase in density” and become “*compacted material*.” (Col. 8, ll. 52-56 (emphasis added).)

U.S. 6,488,801, issued to Bodaghi, et al. on December 3, 2002, discloses a “Method of making media of controlled porosity and product thereof” (Title). The product may, for example, be a medical surgical dressing. (Col. 1, l. 63.) The product may be formed from a web of polymer (such as polypropylene) fibers (col. 7, ll. 1, 23-24) which are heated and compressed by a compaction calendar (col. 8, ll. 60-61 (“The non-woven fabric thus produced is then calendered to compact the same.”); *see also*, col. 11, ll. 27-49). According to Bodaghi, “the unquenched and *uncompacted material* exhibits large pores which may be of sufficient size to allow passage therethrough of both water and water vapor. . . . [W]hen the material is both quenched and compacted, the pore size is further diminished so that the pores pass a limited amount of water vapor, but no water.” (Col. 13, ll. 55-67 (emphasis added).)

*Third Ground of Rejection: claims 1-8 under 35 U.S.C. § 103
as unpatentable over Kreckel*

ISSUE

The issue presented for our review with respect to the third ground of rejection is: have Appellants shown that the Examiner reversibly erred in finding that the claimed “compacted material” reads on Kreckel’s foamed material piece?

We answer this question in the affirmative for the reasons discussed below.

ADDITIONAL FINDINGS OF FACT (“FF”)

10. Kreckel discloses bandage strips for transdermal delivery of drugs. (Abstract.) “[T]he drug formulation is stored in a reservoir, consisting, e.g., of a punched out cavity or of an absorbent piece of material, which is encased or supported by a carrier element (a foamed material piece or a non-woven fleece tape) adhering to the skin by means of a skin-compatible adhesive.” (Abstract.) Kreckel discloses, more specifically, “a foamed material piece (2) containing closed pores” (col. 4, ll. 60-61).
11. The Examiner, relying in particular on col. 4, l. 59-col. 5, l. 38, finds that Kreckel discloses “substantially an anticipation in certain embodiments of the claimed adhesive die cut article of claim 1.” (Ans. 4.) The Examiner concedes that Kreckel does not explicitly disclose a “compacted material,” but maintains that Appellants’ Specification supports a finding that Kreckel’s

foam is a “functional equivalent[] to the claimed compacted material.” (Ans. 5.)

ANALYSIS

The Examiner’s obviousness determination is based on a finding that Kreckel’s foamed material piece is a functional equivalent to the claimed compacted material. For the reasons discussed above, Appellants have persuasively argued that a foam is not necessarily or inherently a “compacted material” as claimed, although a foam may become a compacted material when subjected to appropriate processing steps. Moreover, the Examiner has not identified a teaching or suggestion in Kreckel, or otherwise explained why it would have been obvious, to modify Kreckel’s foam to achieve a “compacted material” as claimed. Accordingly, we are in agreement with Appellants that the Examiner failed to establish a prima facie case of obviousness.

CONCLUSION

Appellants have shown reversible error in the Examiner’s rejections of claims 1-8 under 35 U.S.C. § 112, first and second paragraphs, and under 35 U.S.C. § 103(a) as unpatentable over Kreckel.

Accordingly, we reverse the decision of the Examiner rejecting claims 1-8.

Appeal 2008-1248
Application 10/670,046

REVERSED

ssl

D. PETER HOCHBERG CO. L.P.A.
1940 EAST 6TH STREET
CLEVELAND, OH 44114

Notice of References Cited

Application/Control No.

10/670,046

Applicant(s)/Patent Under
Reexamination

Examiner

Anish Desai

Art Unit

1794

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification	
	A	US-5,497,789	03-1996	Foot protector incorporating a viscoelastic gel	--	--
	B	US-6,488,801	12-2002	Method of making media of controlled porosity and	--	--
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification	
	N						
	O						
	P						
	Q						
	R						
	S						
	T						

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



US006488801B1

(12) **United States Patent**
Bodaghi et al.

(10) **Patent No.:** **US 6,488,801 B1**
(45) **Date of Patent:** **Dec. 3, 2002**

(54) **METHOD OF MAKING MEDIA OF
CONTROLLED POROSITY AND PRODUCT
THEREOF**

(75) Inventors: **Hassan Bodaghi**, Great Neck, NY
(US); **Michael Kauschke**, Rimsting
(DE); **Mordechai Turi**, Princeton
Junction, NJ (US)

(73) Assignee: **First Quality Nonwoven, Inc.**, State
City, PA (US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 337 days.

(21) Appl. No.: **09/594,231**

(22) Filed: **Jun. 14, 2000**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/496,687, filed on
Feb. 2, 2000, which is a continuation-in-part of application
No. 09/460,661, filed on Dec. 13, 1999, which is a contin-
uation-in-part of application No. 09/334,587, filed on Jun. 16,
1999, now Pat. No. 6,413,344.

(51) **Int. Cl.**⁷ **B32B 31/20; B32B 27/02**

(52) **U.S. Cl.** **156/167; 156/181; 156/209;**
156/290; 156/296

(58) **Field of Search** 156/167, 181,
156/296, 308.2, 324, 209, 290

(56) **References Cited**
U.S. PATENT DOCUMENTS

4,112,159 A	9/1978	Pall
4,526,733 A	7/1985	Lau
5,075,068 A	12/1991	Milligan et al.
5,080,569 A	1/1992	Gubernick et al.
5,160,746 A	11/1992	Dodge, II et al.
5,607,701 A	3/1997	Allen et al.
5,804,286 A	9/1998	Quantrille et al.
5,993,943 A	11/1999	Bodaghi et al.
5,997,989 A	12/1999	Gessner et al.
6,001,303 A	12/1999	Haynes et al.
6,176,952 B1	1/2001	Maugans et al.

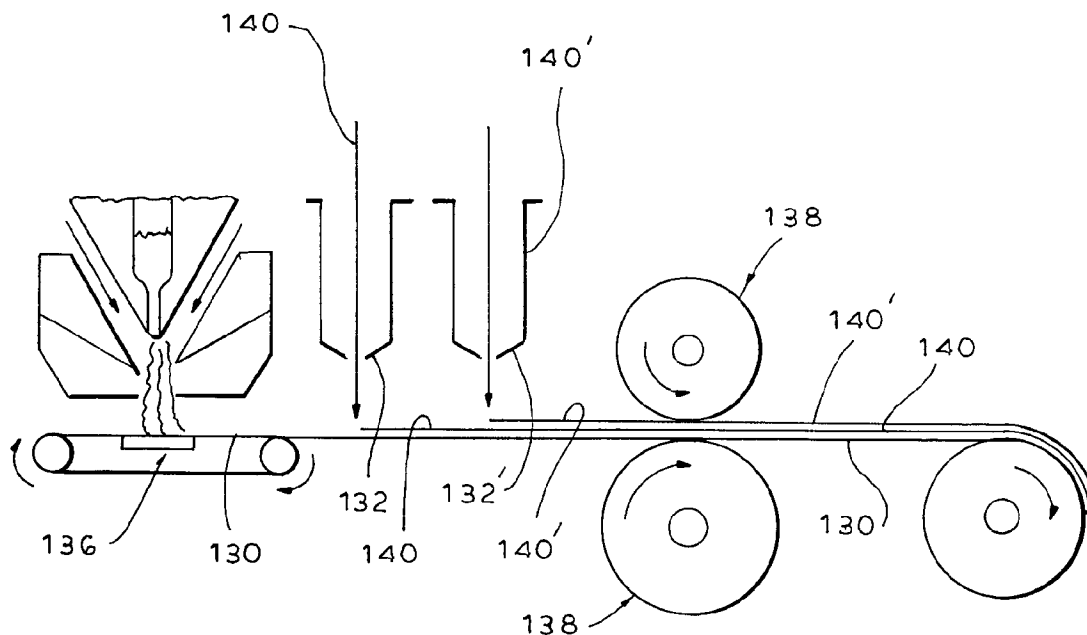
Primary Examiner—Sam Chuan Yao

(74) *Attorney, Agent, or Firm*—Amster, Rothstein &
Ebenstein

(57) **ABSTRACT**

A method of making a non-woven fibrous media, combining high vapor permeability and low liquid permeability, includes the steps of providing a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation and have a wide heat of fusion range distribution, and calendering the fabric to soften the small polymer crystals therein of low heats of fusion, but not the relatively larger polymer crystals therein of relatively higher heats of fusion, thereby to retain high vapor permeability while providing low liquid permeability. The polymer is preferably isotactic polypropylene.

9 Claims, 8 Drawing Sheets



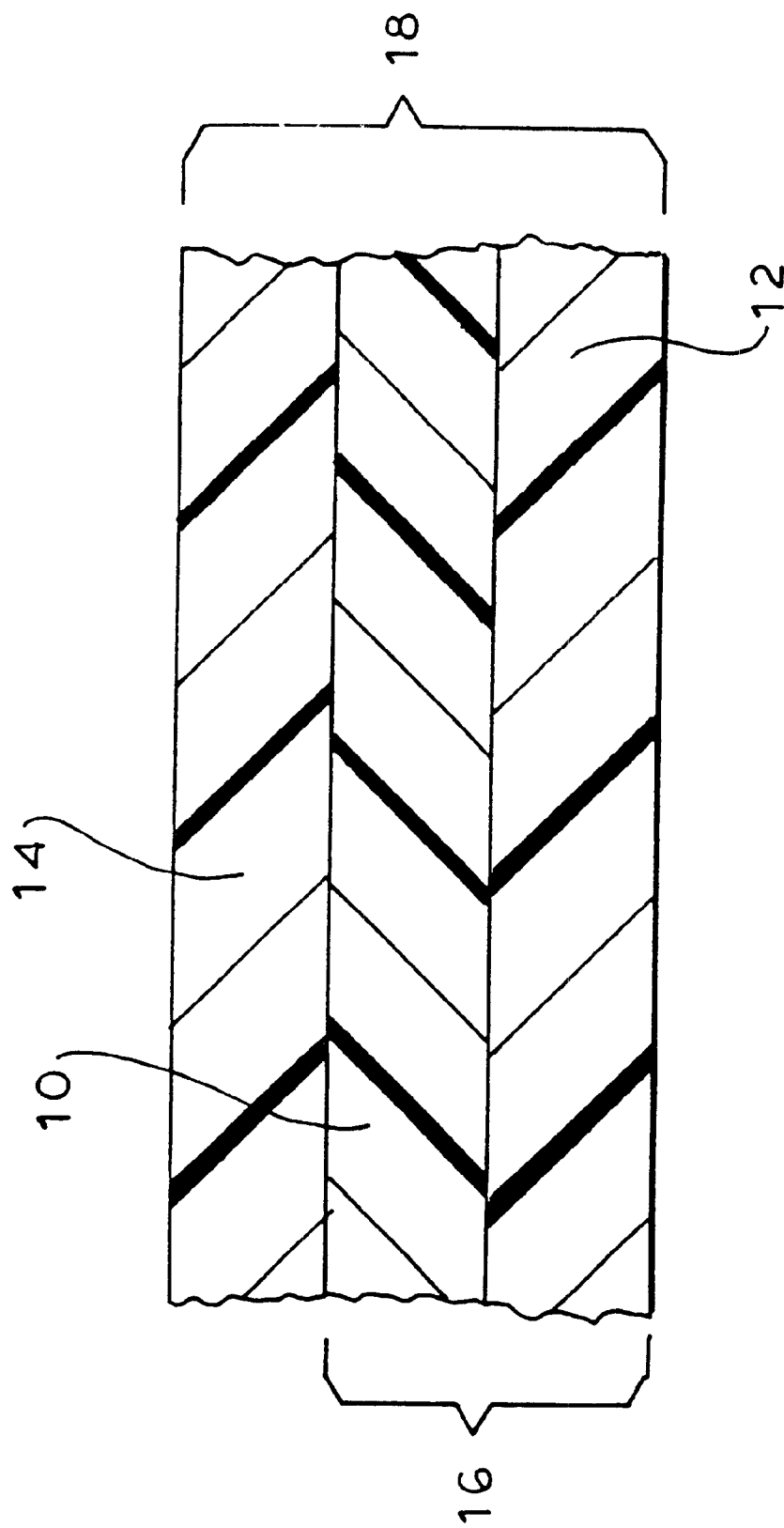


FIG. 1

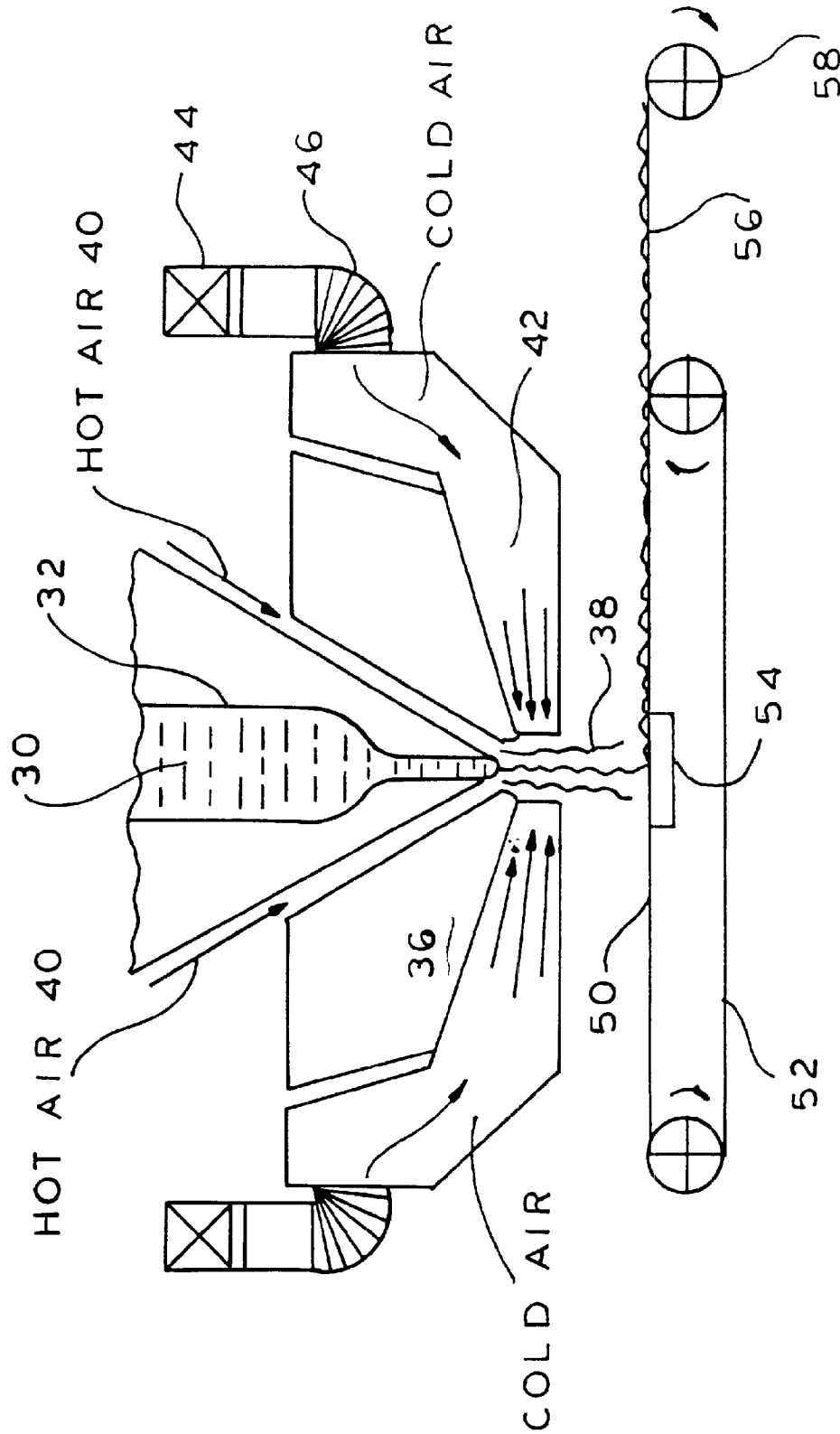


FIG. 2A

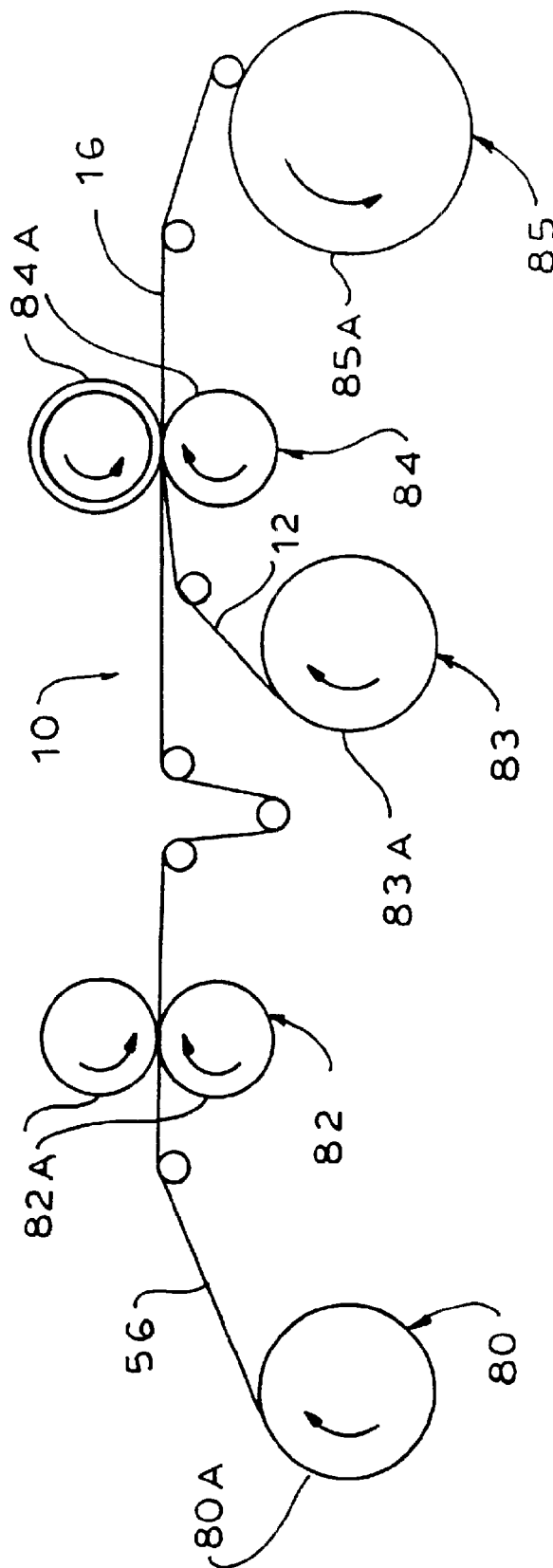


FIG. 2B

FIG. 4

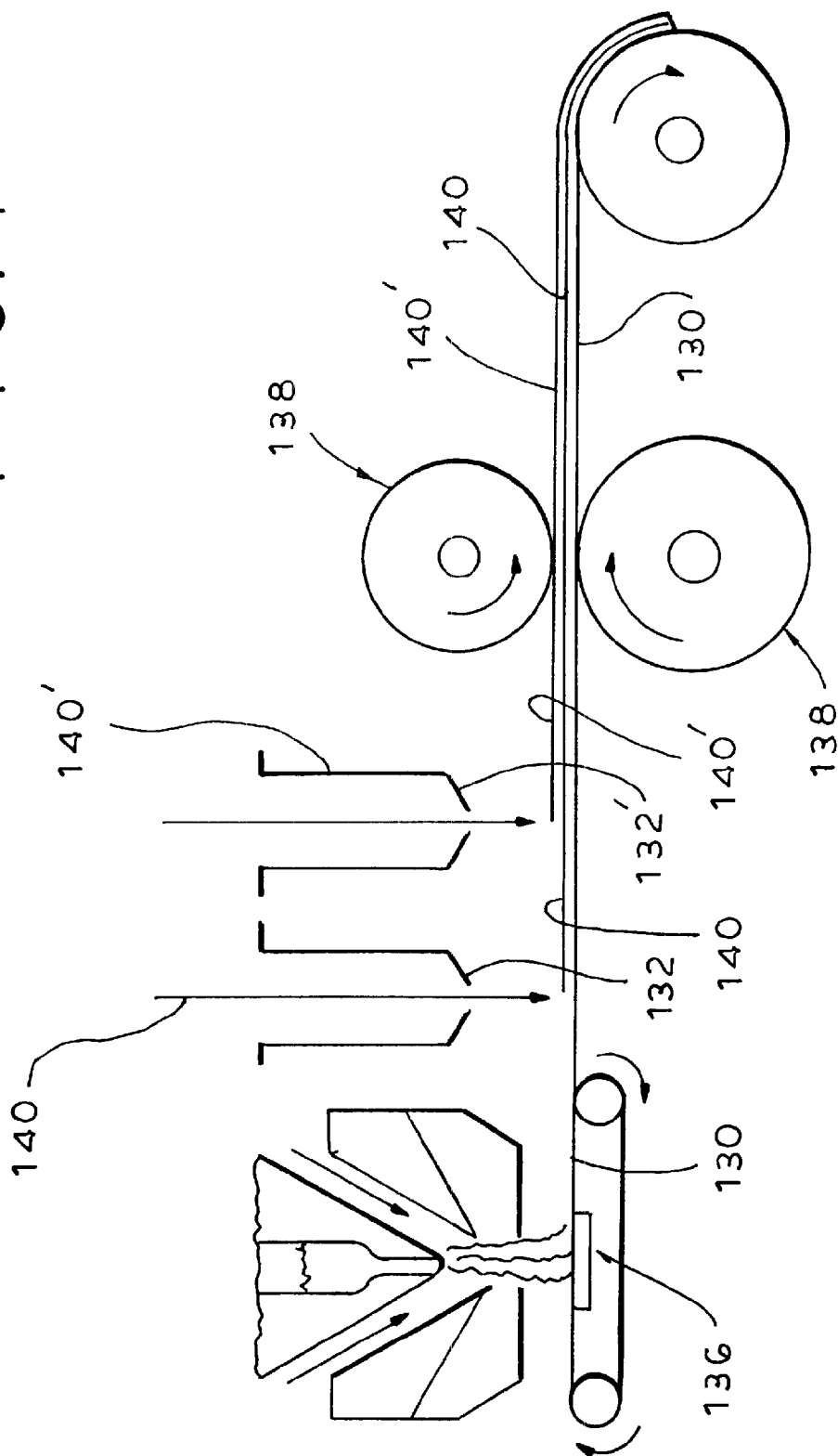


FIG. 5A

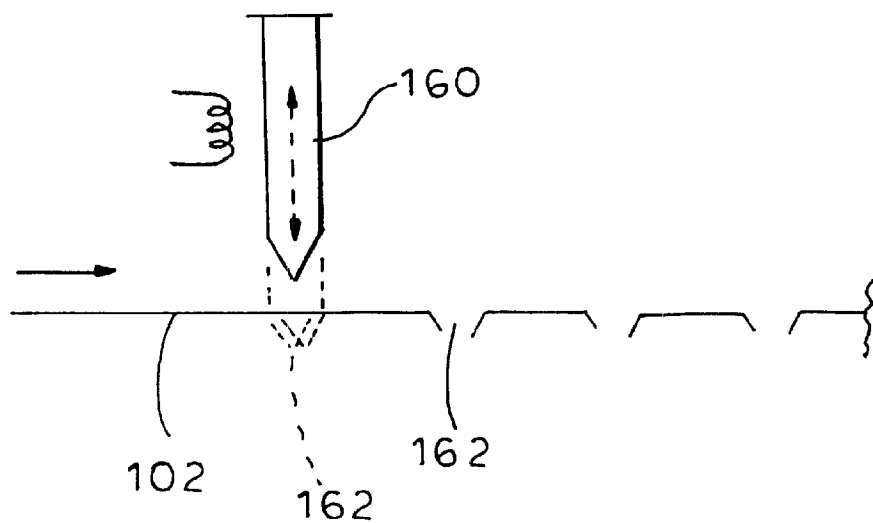
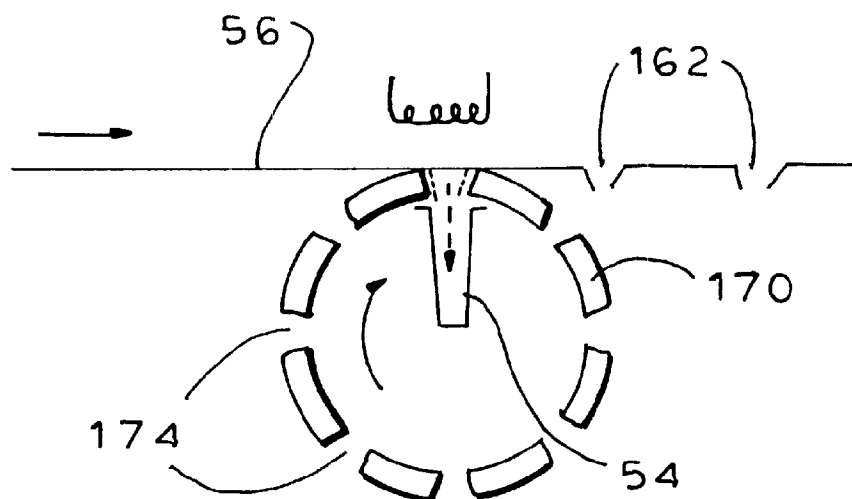
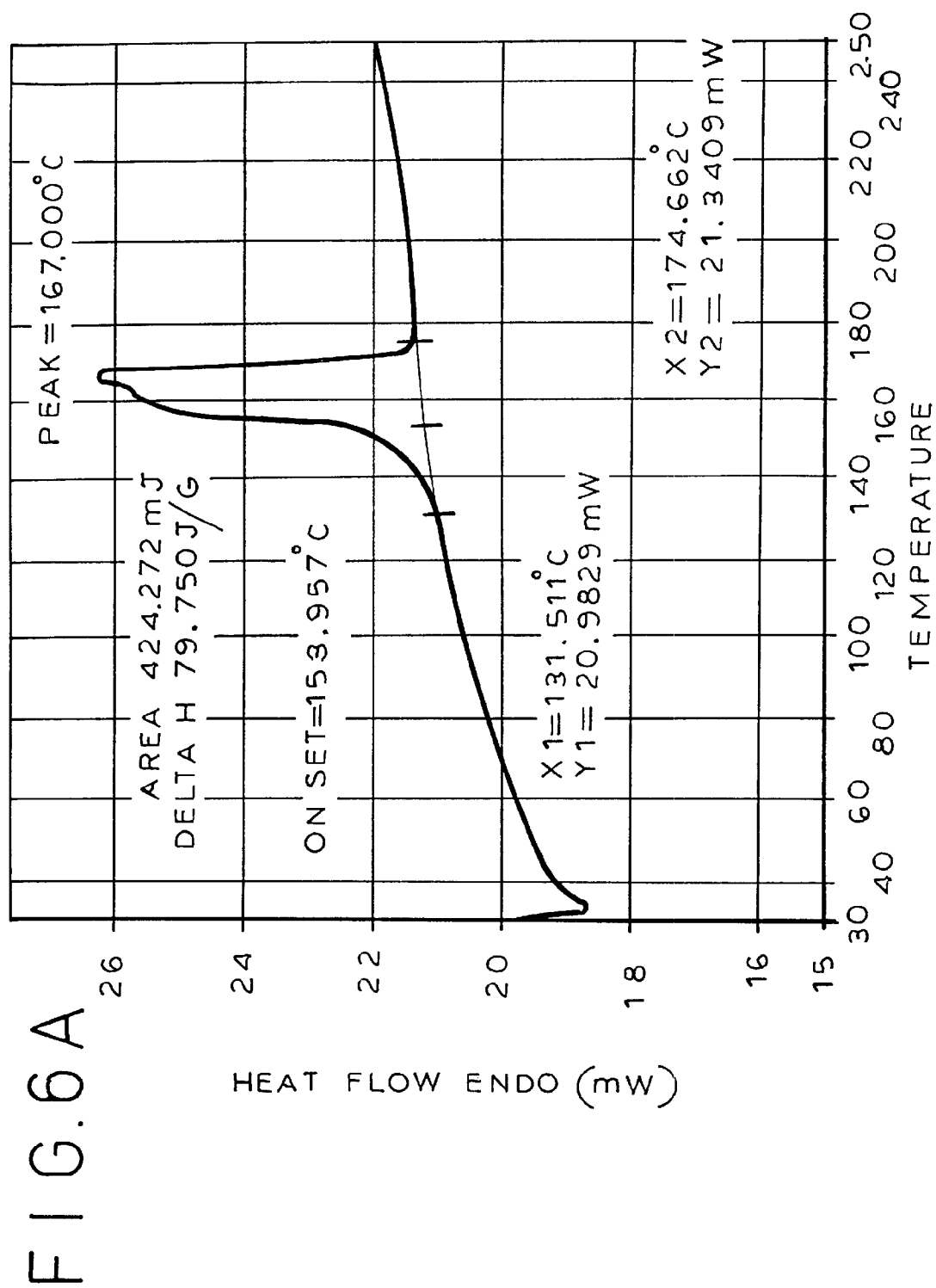
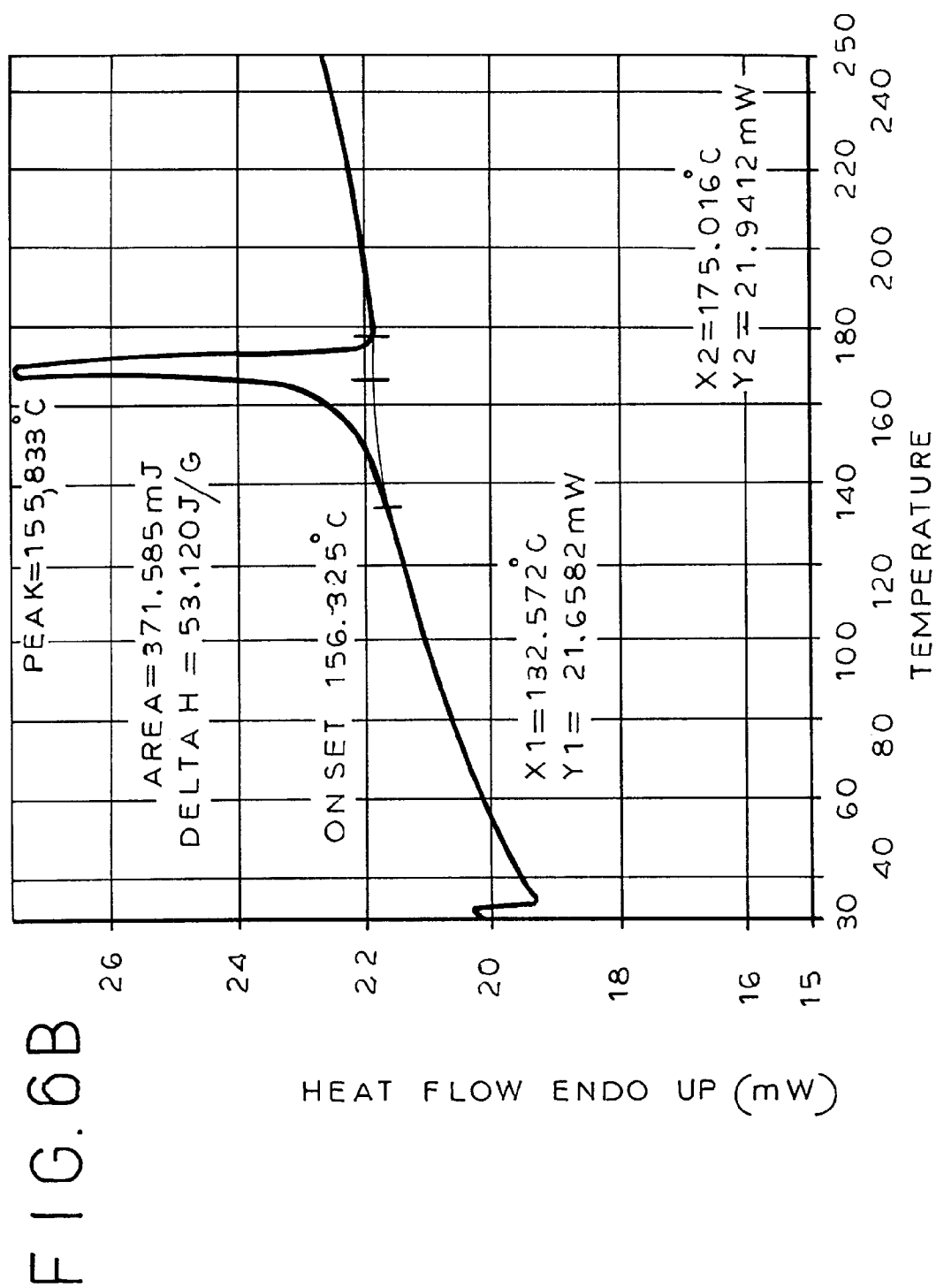


FIG. 5B







METHOD OF MAKING MEDIA OF CONTROLLED POROSITY AND PRODUCT THEREOF

CROSS-REFERENCE TO RELATED APPLICATION

This is a continuation-in-part of U.S. patent application Ser. No. 09/496,687, filed Feb. 2, 2000, itself a continuation-in-part of U.S. patent application Ser. No. 09/460,661, filed Dec. 13, 1999, itself a continuation-in-part of U.S. patent application Ser. No. 09/334,587, filed Jun. 16, 1999 now U.S. Pat. No. 6,413,344 B2.

BACKGROUND OF THE INVENTION

The present invention relates to a method of making fibrous media of controlled porosity, a media having a controlled pore size and a narrow pore size distribution, and a media which combines high vapor permeability and low liquid permeability, and the products thereof.

It is well known to produce a laminate made from various polymers and textiles for use in a wide variety of product applications. For example, meltblown and spunbond materials afford a high level of vapor permeability and liquid permeability when used either by themselves or in combination with one another and/or other porous materials.

Meltblowing is a method for economically producing very small fibers which are mostly suitable for filtration and insulation applications. Fibers smaller than 1 micron in diameter may be produced by meltblowing, and the average fiber diameter in conventional meltblowing is about 4 microns, with fiber size distribution ranging from ¼ micron to 8 microns. To form such small fibers one must start with polymer resins of very low molecular weight. In this process the nonwoven fabric is formed in one step from the polymer resin into the final meltblown nonwoven fabric. Meltblown fabrics are porous and, significantly, do not have either a controlled pore size or a narrow pore size distribution. Instead, pore size is random and non-uniform, such that a typical meltblown fabric will have a random distribution of pores of various sizes. A meltblown fabric having a controlled pore size and a narrow pore size distribution would have great utility in particular applications—filtration applications, for example. One embodiment of the present invention relates to a meltblown fabric having a controlled pore size and a narrow pore size distribution.

In contrast, spunbonding is very similar to conventional fiber spinning where several processing steps are required to form the spunbond fabric. Spunbond fibers go through a drawing stage and then a laydown stage wherein the drawn fibers are laid down into a matt and the matt is then bonded by a thermobonding calender or mechanical entangling to form the nonwoven fabric. The resins used in the spunbonding process have lower molecular weight than those used in the conventional melt spinning process and higher molecular weights than those used in the conventional meltblowing process. Fibers smaller than 10 microns in diameter are very difficult to produce economically by spunbonding, and the average fiber diameter for conventional spunbonding processes is about 18 microns.

However, for particular applications, such as those in the health care industry—e.g., infant diapers, sanitary pads, adult incontinence wear, medical surgical dressings, and the like—the product must perform three distinct functions: First, a front or top sheet intended to contact the patient's skin must allow the passage of moisture (e.g., blood, urine and like liquids) therethrough while at the same time pro-

viding an acceptable feel to the wearer's skin. Second, an absorbent core, intermediate the topsheet and the backsheet, must be capable of absorbing the moisture which has been received through the topsheet. Third, a backsheet, on the back of the absorbent core, prevents leakage of moisture outwardly of the laminate. Another embodiment of the present invention relates specifically to the backsheet component.

The barrier properties of the backsheet (i.e., the trapping of moisture and other liquids) are typically achieved by incorporating into the backsheet a plastic layer or film which acts as a moisture barrier. Various major disadvantages associated with the utilization of such barrier films are the low moisture vapor transmission rates (MVTR) of the barrier films, undesirable crinkling noise created by the barrier film during usage of the product, and a stiffening of the product (due to the barrier film) which reduces its conformability to the area to which it is applied.

Porous films are typically permeable to both liquid water and water vapor. They may be made by the incorporation of different organic or inorganic additives into a polymer film, the film then being stretched or fillers removed therefrom chemically. Other conventional methods include mechanical perforation and/or radiation techniques to form the desired holes or slits in the polymeric film. Formation of uniform pore size in a film is very difficult, and porous plastic films are generally more expensive than non-wovens.

On the other hand, non-porous barrier films are typically impermeable to both liquid water and water vapor. As a result, using the impermeable film in a diaper backsheet, for example, makes the diaper hot before exposure to liquid (as the barrier film prevents air circulation) and clammy after exposure to moisture (because the barrier film precludes moisture evaporation). Indeed, the use of an impermeable barrier film in a diaper may cause severe dermatological problems, such as skin rash on infants, and skin sores on adults wearing such non-porous products.

It is also known to form a semi-porous barrier film of controlled porosity which is permeable to water vapor, but impermeable to liquid water—that is, breathable. However, the method of manufacturing such a microporous film of controlled porosity is typically complex and expensive, and requires a relatively specialized polymeric input (for example, conjugate fibers formed of two separately manufactured polymeric materials or laminates formed of two separately manufactured polymeric materials).

Clearly the need remains for a method of economically manufacturing a media of controlled porosity, and in particular a media of controlled porosity that includes high vapor permeability and low liquid permeability, without the use of chemical binders, additives or coatings. Such breathable media would find use in products which are sold in such quantity that any reduction in the cost thereof (e.g., which makes it sufficiently economical for manufacture for use in disposable products) is highly desirable.

Accordingly, it is an object of the present invention to provide, in one embodiment, a method of making of a media of controlled porosity.

Another object of the invention is to make, in one embodiment, a media of controlled porosity combining high vapor permeability and low liquid permeability.

Still another object is to provide such a method which, in one embodiment, does not require a specialized polymeric input.

A further object is to provide such a method which, in one embodiment, does not require the use of chemical binders, additives or coatings to provide the desired permeability or porosity.

It is also an object of the present invention to provide, in one embodiment, a material made by the aforesaid method.

It is another object to provide, in one embodiment, such a material which does not produce noise during use and which exhibits cloth-like feel (hand).

It is a further object to provide, in one embodiment, such a material which is economical to manufacture (e.g., for use in disposable products).

SUMMARY OF THE INVENTION

It has now been found that the above and related objects of the present invention are obtained in a method of making a non-woven fibrous media of controlled porosity, the method comprising the step of providing a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein having relatively higher heats of fusion. In a preferred embodiment, the fabric is a meltblown fabric formed from meltblown fibers.

The present invention also includes a method of making a non-woven fibrous media combining high vapor permeability and low liquid permeability. The method comprises the steps of providing a non-woven fabric formed from fibers that are prematurely crystallized during web formation and have a wide heat of fusion range distribution, and then calendering the fabric to soften the small polymer crystals therein of low heats of fusion, but not the relatively larger crystals therein of relatively higher heats of fusion, thereby to retain high vapor permeability.

The present invention additionally comprises a non-woven fibrous media providing a controlled porosity with a narrow pore size distribution and/or a non-woven fibrous media providing high vapor permeability and low liquid permeability. The media is a non-woven fabric formed from fibers that are prematurely crystallized polymer and have a wide heat of fusion range distribution. To achieve high vapor permeability and low liquid permeability, the fabric is then calendered to soften the small polymer crystals therein of low heats of fusion, but not the relatively large polymer crystals therein of relatively higher heats of fusion, thereby to retain high vapor permeability while providing low liquid permeability.

In a preferred embodiment the polymer is polypropylene, and optimally isotactic polypropylene, although other isotactic polymers may be used. The polymer is prematurely crystallized, preferably by quenching it prior to completion of fiber structural formation so that the polymer exhibits a bell-shaped heat of fusion range distribution (prior to calendering). Pore size is controlled by the speed of quenching. The faster the quenching, the smaller the pore size. The temperature, pressure and roller speed of the calendering operation are selected to soften the small polymer crystals, but not the relatively larger polymer crystals. For example, the fabric is preferably calendered at a temperature of about 25–110° C., a pressure of about 25–150 Newtons, and a roller speed of up to 200 meters/minute. The fabric is calendered to retain a moisture vapor permeability of at least about 1200 g/m² @ 24 hours and to provide a hydrostatic head of at least about 10 millibars (about 100 mm H₂O). The calendered material may be made into a composite with, for example, at least one spunbond, spunmelt or other non-woven fabric layer.

The present invention also relates in particular to five separate process modifications and the products thereof.

The first process modification is a method of making a fibrous media combining high vapor permeability and low

liquid permeability. The method comprises the steps of providing a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion. The fabric is calendered to soften the small polymer crystals therein of low heats of fusion, but not the relatively larger polymer crystals therein of relatively higher heats of fusion, thereby to retain high vapor permeability while providing low liquid permeability. A laminate is formed of the calendered fabric and a non-woven, and the laminate is passed through an embossing station to impose a pattern of depressions and projections on the calendered fabric wherein the non-woven enters the depressions of the embossed calendered fibers. Preferably, the laminating station includes a heated hard roll adjacent the non-woven and an unheated soft roll adjacent the calendered fabric, and the calendered fabric retains after lamination a high MVTR and substantially no holes therein. Preferably, the non-woven is a spunbond.

The product of the first process modification is a non-woven fibrous media combining high vapor permeability and low liquid permeability. The media comprises a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion. The fabric is calendered to soften the small polymer crystals, but not the relatively larger polymer crystals, thereby to retain high vapor permeability while providing low liquid permeability. The non-woven fabric is a component of a calendered laminate with a spunbond, the non-woven fabric having an embossed pattern of depressions and projections, with the spunbond entering the depressions of the non-woven fabric.

The second process modification is a method of making a fibrous media combining high vapor permeability and low liquid permeability. The method comprises the steps of providing a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion. The prematurely crystallized fibers of the fabric are passed through an addition station where at least one polymeric addition material is deposited on the fibers. The fabric is then calendered to soften the small polymer crystals therein of low heats of fusion, but not the relatively larger polymer crystals therein of relatively higher heats of fusion, thereby to retain high vapor permeability while providing low liquid permeability, and to integrate the fabric and the addition material. Preferably, the fibers are polypropylene of a given diameter range, and the addition material is selected from the group consisting of polyethylene, polyurethane, ethyl vinyl alcohol, polypropylene of a different diameter range, and combinations thereof. Substantially each addition material is added at a respective separate addition station.

The product of the second process modification is a non-woven fibrous media combining high vapor permeability and low liquid permeability. The media comprises a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion. The fabric is calendered to soften the small polymer crystals, but not the relatively larger polymer crystals, thereby to retain high vapor permeability while providing

low liquid permeability. The calendered fabric includes at least one polymeric addition material deposited on the fabric. Preferably, the at least one polymeric addition material is deposited on the fabric before or after calendering.

The third process modification is a method of making a fibrous media combining high vapor permeability and low liquid permeability. In one embodiment, the method comprises the steps of providing a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion. The fabric is calendered to soften the small polymer crystals therein of low heats of fusion, but not the relatively larger polymer crystals therein of relatively higher heats of fusion, thereby to retain high vapor permeability while providing low liquid permeability. The size of the pores in the calendered fabric is increased, and the pores in the calendered fabric are shaped so as to maximize strikethrough of bodily fluids and minimize rewetting. Preferably, the increasing and shaping step comprises hot needle perforation of the calendered fabric such that insertion of the hot needle plasticizes the calendered fabric thereabout and, upon withdrawal of the hot needle, allows freezing of the plasticized calendered fabric. In another embodiment, the method comprising the steps of providing a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion. A perforated rotating screen under suction is used to receive the fibers of the fabric and form enlarged and shaped pores therein to maximize strikethrough and minimize rewetting. The fabric is then calendered to soften the small polymer crystals therein of low heats of fusion, but not the relatively larger polymer crystals therein of relatively higher heats of fusion, thereby to retain high vapor permeability while providing low liquid permeability.

The product of the third process modification is a non-woven fibrous media combining high vapor permeability and low liquid permeability. The media comprises a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion. The fabric is calendered to soften the small polymer crystals, but not the relatively larger polymer crystals, thereby to retain high vapor permeability while providing low liquid permeability. The non-woven fabric defines enlarged and shaped pores to maximize strikethrough and minimize rewetting.

The fourth process modification is a method of making a fibrous media combining controlled vapor permeability and low liquid permeability. The method comprises the steps of providing a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion. The fabric is calendered to soften substantially all of the small polymer crystals therein of low heats of fusion, and a controlled proportion of the relatively larger polymer crystals therein of relatively higher heats of fusion, thereby to control vapor permeability while providing low liquid permeability.

The product of the fourth process modification is a non-woven fibrous media combining controlled vapor permeability and low liquid permeability. The media comprises

a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion. The fabric is calendered to soften substantially all of the small polymer crystals, and a controlled proportion of the relatively larger polymer crystals, thereby to control vapor permeability while providing low liquid permeability.

The fifth process modification is a method of making a fibrous laminate combining high vapor permeability and low liquid permeability. The method comprises the steps of providing a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion. The fabric is calendered to soften the small polymer crystals therein of low heats of fusion, but not the relatively larger polymer crystals therein of relatively higher heats of fusion, thereby to retain high vapor permeability while providing low liquid permeability. The multi-layer laminate is formed of the calendered fabric with a high strength spunbond on each side of the calendered fabric.

The product of the fifth process modification is a non-woven fibrous laminate combining high vapor permeability and low liquid permeability. The laminate comprises a non-woven fabric formed from fibers that are prematurely crystallized during fabric formation to form small polymer crystals therein having low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion. The fabric is calendered to soften the small polymer crystals, but not the relatively larger polymer crystals, thereby to retain high vapor permeability while providing low liquid permeability. The calendered fabric is an intermediate layer of a multi-layer laminate having a high strength spunbond layer on each side thereof.

BRIEF DESCRIPTION OF THE DRAWING

The above and related objects, features and advantages of the present invention will be more fully understood by reference to the following detailed description of the presently preferred, albeit illustrative, embodiments of the present invention when taken in conjunction with the accompanying drawing wherein:

FIG. 1 is an isometric view of a fabric according to the present invention, laminated to a spunbond fabric, for use in a diaper;

FIGS. 2A and 2B form a flow chart of a preferred method of making the fabric;

FIG. 3 is a schematic side elevational view of the process of embossing or patterning a compacted meltblown/spunbond material of the present invention to form an embossed laminate;

FIG. 4 is a schematic side elevational view of the process for adding addition materials to the main meltblown polymer at addition stations upstream of the compacting station;

FIG. 5A is a fragmentary enlarged schematic sectional view showing penetration of a compacted meltblown material by a hot needle to perforate the same;

FIG. 5B is a fragmentary side elevational view showing the use of a perforated rotating screen on a section box to perforate the hot meltblown material prior to compaction; and

FIGS. 6A and 6B are DSC curves for a quenched meltblown and a non-quenched meltblown, respectively.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawing, and in particular to FIGS. 1 and 2 thereof, the present invention relates to a method of

making a non-woven fibrous media of controlled porosity, generally designated by the reference numeral **10**, the media **10** optionally combining high vapor permeability and low liquid permeability. While for the purposes of the present invention, the media will be described as combining high water vapor permeability and low liquid water permeability, clearly the intended application of the media will dictate the specifics of these criteria—for example, whether the low liquid permeability applies to blood, bodily exudate or like liquids and whether the high vapor permeability applies to water vapor, air or like gases. Typically, the goal is a substantially water liquid impermeable and substantially water vapor permeable media. The optimum balance of properties can be tailored for individual applications.

The molten polymer from which the media will be made is preferably isotactic in nature so that it has a uniform structure over its polymeric chain length. Alternatively, however, syndiotactic polymer may be used in particular applications where the uniformity of the structure is of lesser importance. Atactic materials are not suitable for the purpose of the present invention since the structure thereof is so irregular over its polymeric chain length that they strongly resist crystallization. Polyolefins are preferred for use as the polymer, polypropylene being especially preferred. Thus, the preferred polymer for use in the present invention is isotactic polypropylene.

Typically, pellets or other conventional forms of the polymer suitable for handling within a manufacturing plant are placed in the hopper of a spinnerette and melted through an extruder. Once molten, the polymer is forced (extruded) through a spinnerette die defining small nozzles through which the molten polymer passes, thereby forming fibers as the polymer cools. For ease of processing, the polymer preferably has a very high melt flow level rate and is collected from the spinnerette die at very close die-collector distances. While the non-woven fabric is preferably a meltblown, it may also be a spunbond or other non-woven fibrous media to the extent that a suitable fabric is produced.

It is a feature of the present invention that the fabric be formed from fibers that are prematurely crystallized during fabric formation. Such prematurely crystallized fibers exhibit a “smectic” crystalline structure. A smectic crystalline structure contains both small polymer crystals of low heat of fusion and relatively larger polymer crystals of relatively higher heats of fusion. The smectic crystalline structure is also referred to as “paracrystallinity.”

The smectic or prematurely crystallized nature of the fibers useful in the method of the present invention can be achieved in a variety of different ways. The most common technique is to quench the fibers emerging from the spinnerette die (e.g., with a cold gas or liquid, such as air at or below 23° C. or ambient temperature) before all of the polymer crystals in the fibers have grown to their full extent. As a result, the quenched fibers will contain small polymer crystals of low heats of fusion and relatively larger polymer crystals of relatively higher heats of fusion. In other words, prematurely crystallized fibers exhibit a wide range distribution of the heats of fusion.

That the quenched polymer fibers exhibit a relatively wide heats of fusion distribution is evidenced by the relatively broad bell-shaped curve distribution observed in the DSC (Differential Scanning Calorimeter) data therefor. To obtain the DSC data, the polymer fibers are heated from 30° C. to 300° C. at a temperature increase rate of 10° C./minute. The heat of fusion data is plotted in FIGS. **6A** and **6B** as heat of fusion (Heat Flow Endothermic Up) in milliwatts versus

temperature in ° C. The “area” under the curve represents the amount of heat absorbed, and the “ ΔH ” represent the heat of fusion.

As seen in FIG. **6B**, typically a non-quenched polymer (100% polypropylene) exhibits a narrow heat of fusion range distribution peak, indicating that all the polymer crystals thereof are of roughly the same morphology—i.e., have comparable heats of fusion so that they all soften at the same temperature. By way of contrast, smectic polymer contains some polymer chains that are highly crystallized and other polymer chains that are less highly crystallized. As a result, as seen in FIG. **6A**, the smectic polymer (100% polypropylene) of the present invention typically exhibits a relatively wide range of heats of fusion, as evidenced by the relatively broad bell-shaped curve distribution (as opposed to the narrow peak distribution of non-smectic polymer). Indeed, the DSC curves for a smectic polymer typically indicate two peaks, a major peak and a minor peak within the major peak, while the DSC curves for a conventional non-smectic polymer exhibit only a single peak.

The data in TABLE III shows that the quenched polymer fibers of Sample 1 exhibit a sharply reduced air permeability relative to non-quenched like polymer fibers of Sample 2. For a 100% polypropylene fiber, the air permeability of the unquenched fiber (Sample 2) is 193, while the air permeability for the quenched fiber (Sample 1) is reduced to 83. A similar reduction in permeability is obtained for fiber blends.

At this juncture, it should be appreciated that the distinction between the small polymer crystals and the relatively larger polymer crystals in the smectic material reflects not a difference in the molecular weights of the polymer crystals (i.e., the degree of polymerization thereof), but rather a difference in the morphology of the polymer crystals themselves. Typically the molten polymeric material which is passed through the spinnerette has polymer chains of generally the same molecular weight. Even where the pellets themselves are characterized by a wide molecular weight range, the initial processing thereof by heat and pressure in the spinnerette hopper acts to make them of a generally uniform molecular weight. Rather the “smectic crystallization” (or the “premature crystallization” or “supracrystallinity”), as applied to the present invention, relates to the morphology of the polymer crystals.

While various techniques may be used to achieve the premature crystallization of the fibers, it is most easily and economically achieved by rapid quenching of the fibers by liquid or gas cooling as the fibers leave the die of the spinnerette and approach the web of the collector. With the exception of the premature crystallization of the fibers during fabric formation, the production of the non-woven fabric according to the present invention is conventional in nature, and typically reflects well known non-woven fabric production techniques, especially those used in the production of meltblown fabrics. The quench temperature at which the molten filaments are quenched will depend, to some degree, on the composition of the molten polymer **30**. For isotactic polypropylene a quench temperature of 23° C. or below is preferred.

The non-woven fabric thus produced is then calendered to compact the same. The roll surface temperature, roll surface pressure and roll speed of the calender are selected so as to soften the small polymer crystals (of relatively low heats of fusion), but not the relatively larger polymer crystals (of relatively higher heats of fusion), thereby to retain high vapor permeability. For example, a preferred smectic polypropylene meltblown fabric is calendered at a roll

surface temperature of about 25–110° C., a roll surface pressure of 25–150 Newtons, and a roll speed of up to 200 meters per minute to form a medium **10** of the present invention.

Roll speeds in excess of 200 meters per minute typically do not provide adequate time for heating of the fabric passing through the calender nip. On the other hand, roll speed should be maintained at as high a level as possible in order to provide increased production rates.

Generally speaking, as the pressure and temperature of a calendering operation are increased, the crystallinity of the resultant medium (as measured by the increase of the area under the peaks of a DSC curve) also increases. If the temperature and pressure applied by the calendar are too low (or the roll speed too high), then the undercalendered meltblown fabric retains its high porosity to both liquid and gas and cannot act as a barrier sheet. If the temperature and pressure of the calender are too high (or the roll speed too low), then the overcalendered meltblown fabric is converted into a film which is totally impermeable to both gas and liquid (and noisy in use as well). Clearly, the optimum temperature, pressure and roll speed will depend on the nature of the particular smectic polymer being processed. While the degree of vapor permeability and liquid impermeability (hydrohead) will vary with the particular intended application of the product, typically a substantially complete liquid impermeability (even at a hydrostatic head of at least about 10 millibars) and a substantial complete vapor permeability (that is, a vapor permeability of at least about 1200 g/m² @ 24 h) are preferred.

The preferred pressure and temperature parameters for the compacting step may be easily and rapidly determined for any quenched material by holding one of the temperatures and pressures variables constant, while varying the other variable. Generally, the higher compacting temperatures are required in order to obtain air permeabilities and MVTRs within the preferred ranges, and the higher compacting pressures are required to obtain higher hydroheads.

It will be appreciated that air permeability and moisture vapor transmission rates are not necessarily related. Air permeability is closely related to the compactness of the material being measured and its resistance to air flow therethrough, while MVTR is more related to the morphology of the material being measured and its resistance to moisture vapor transmission flow. Nonetheless, as a practical matter, air permeability measurements may be taken as indicative of MVTR measurements, subject to correction as necessary, where, for example, the MVTR measuring equipment is unavailable and the air permeability measuring equipment is available.

It is theorized that during calendering the small polymer crystals (with low heats of fusion) soften and act as a binder between the unsoftened larger polymer crystals (with high heats of fusion). It is theorized that the softening of the small polymer crystals allows them to close the pores between the large polymer crystals, thereby shrinking the fabric and forming a vapor permeable, liquid impermeable non-woven barrier medium. The calendering effects fiber shrinkage and contraction in the media, thereby closing the large liquid-bearing channels or pores therethrough while leaving open the relatively smaller vapor-bearing channels or pores therethrough.

The optimum balance of properties can be tailored for particular applications.

It will be appreciated by those skilled in the art that the term "calender," as used herein, encompasses all means to

perform both heat transfer and compacting (that is, heating and reducing the thickness of a fabric). While a set of calender rolls is the most common mechanism for performing these operations, other mechanisms may be used instead or in addition thereto.

The media **10** is characterized by a hydrohead of at least about 10, and preferably at least 20 millibars, an MVTR of at least about 1200, and preferably at least 3000 g/m² @ 24 h, and an air permeability of about 0.1–100, and preferably 0.4–3 cfm. The laminated composite **16** (formed of the media **10** and a spunbond fabric **12**) suitable for use as a backsheet in a diaper or other absorbent product, has a hydrohead of at least about 20, and preferably 30 millibars, an MVTR of at least about 2000, and preferably 4000 g/m² @ 24 h, and an air permeability of about 0.05–3, and preferably 0.1–1 cfm. These criteria are set forth in Table A below.

TABLE A

	HYDROHEAD mbr	MVTR g/m ² @ 24 h	AIR PERMEABILITY cfm
Media	≥10 (≥20)	≥1,200 (≥3,000)	0.1–100 (0.4–3)
Composite	≥20 (≥30)	≥2,000 (≥4,000)	0.05–3 (0.1–1)

Legend: () = preferred values

With regard to the data of TABLE A, it will be appreciated that the upper limits on the air permeability exists because, if material has too high an air permeability, it will probably leak liquid as well as air. While there is no upper limit set for the moisture vapor transmission rate (MVTR), it is generally preferred that the MVTR not be so high as to produce a clammy feeling or chill due to a rapid evaporation of the water.

No upper limits are given for the hydrohead because, as a practical matter, no liquid permeability is desired, regardless of the amount of pressure being exerted on the liquid trapped by the media and/or composite. When the media and/or composite is used as the backsheet of an infant diaper, the pressure exerted thereon (that is, primarily the weight of the infant) will be minimal so that the indicated minimal values of the hydrohead for the media/composite are acceptable. On the other hand, when the media/composite is used as the backsheet of an adult diaper or an adult incontinence pad, clearly a much higher hydrohead is required to prevent the escape of liquid under the weight of the adult. Thus, for example, hydroheads of 120 millibars would be the minimum for a backsheet of an adult diaper intended for use by a 180 lb. person. It will be appreciated that the infant/adult difference will also play a role in the quantity of moisture (i.e., urine) which must be allowed to escape as moisture vapor, depending upon the size and health of the kidneys of the wearer. The MVTR rates set forth are appropriate for the accommodation of both infants and adults.

The products of the invention are characterized by a relatively high tensile strength (both MD and CD) relative to competitive products. A medium **10** according to the present invention was laminated on one side to a conventional spunbond fabric **12** and on the other side to a conventional meltblown fabric **14**, to form a fabric **18** as illustrated in FIG. 1. The sample thus prepared had a hydrohead of 164 millibars and a moisture vapor transmission rate (MVTR) of 4411 g/m²/@24 h. In practical terms, the specimen exhibited essentially no liquid leakage and a very high moisture vapor permeability relative to other commercial diaper backsheet specimens of comparable basis weight.

Referring now to FIG. 2 in particular, FIG. 2A illustrates the formation of a thermally sensitive meltblown smectic web and FIG. 2B illustrates the compacting of the web and the optional lamination thereof to form an SM laminate 16.

Referring now to FIG. 2A in particular, the molten polymer 30 is extruded through a spinnerette or die hole 36 to form filaments 38. At the same time, hot air 40 is directed into the die body and emerges close to the filaments 38 being formed (adjacent the spinnerette) to draw the molten filaments 38. The molten filaments are then immediately quenched via chilled air 41 (for example, at about or below 23° C. or ambient temperature) as they are fed into a quenching unit 42 via a fan 44 and piping 46 so that the drawn filaments 38 are prematurely quenched by the cold air, thereby resulting in the formation of a material containing both small polymer crystals and large polymer crystals. The prematurely quenched filaments 38 then fall onto a collector 50 comprised of a roll or a conveyor belt 52, under the influence of gravity and/or a suction box 54, to form a thermally sensitive meltblown smectic web 56. The meltblown web 56 is eventually collected on a take-up roll 58 for storage or used immediately in the next step of the process. The meltblown web 56 is a media of controlled porosity and optionally combines high vapor permeability and low liquid permeability. Such materials find utility as filters in a variety of different applications, and the like.

Referring now to FIG. 2B in particular, a thermally sensitive meltblown smectic web 56 is unwound from a supply drum 80 A thereof at the unwinding station 80. The web is then passed through a compacting station 82. The compaction calender 82 A of compacting station 82 has two rolls. The top roller has a smooth steel outer surface and thermal oil heating so as to provide a controlled temperature at the calender nip. The bottom roll is made of a softer material as compared to steel (e.g., a polyamide available under the trade name RACOLON) which make the media softer during compacting and prevents possible pinholes as the media gets thinner. The simultaneous heating and compression of the fabric fibers by the compaction calender 82 A imparts liquid impermeability (barrier properties) to the medium of the present invention while retaining, at least to some degree, the gas permeability (breathability) thereof. The calendering effects fiber shrinkage and contraction in the media, (due to the heat effect of calendering) thereby closing the large liquid-bearing channels or pores there-through while leaving open the relatively smaller vapor-bearing channels or pores therethrough. The output of compacting station 82 is a media 10 according to the present invention.

However, to enhance the strength and feel thereof, the media 10 is typically laminated together with at least one spunbond, spinnelt or other nonwoven fabric on one side thereof, and optionally a meltblown or second spunbond, spinnelt or other nonwoven fabric on the other side thereof. Thus, at unwinding station 83 a spunbond material 12 is unwound from a supply drum 83A thereof. The compacted meltblown media 10 and the spunbond material 12 are laminated together at a laminating station 84 by a lamination calender 84A to form a laminate 16. The lamination calender has a rubber-covered steel roll adjacent the media and an engraved roller adjacent the spunbond material.

Other materials with which the media 10 may be laminated include cellulosic fibers (paper pulp), synthetic fibers, and even woven textiles.

Special roll combinations in the laminating station 84 may be used to affect the strength and textile-like softness (hand)

of the final product, as well as adding desirable patterns to the fabric for aesthetic reasons. Preferably, the final product 16 (or 18 if a third layer is added) has a cloth-like feel combined with high tensile and related strength characteristics. The textile-like characteristics of the medium 10 are especially desirable where the fabric is used alone, although they may also be desirable when the medium 10 is used as an outer layer of a laminate.

In take-up station 85, the composite output 16 of lamination station 84 is wound on a take-up roll 85A.

In the description above and the examples below, the important variables were determined using internationally accepted tests as follows:

Hydrohead: EDANA-ERT-160-89

Air Permeability: EDANA-ERT-140.1-81

Mechanical (Tensile) Properties: EDANA-ERT-20.2-89

Basis Weight: EDANA-ERT-40.3-90

MVTR: ASTM-E96E

EXAMPLES

Example I

In order to establish the porosity of a medium according to the present invention, a diaper backsheet made with a preferred product of the present invention was compared with the backsheets of several competitive commercial diapers, with the results provided below in Table I.

The backsheet product of the present invention (labeled "FOF" in TABLE 1) was a SMM fabric containing on one side 10 g/m² of spunbond fabric, in the middle 10 g/m² of smectic media compacted according to the present invention, and on the other side 10 g/m² of uncompressed meltblown fabric, for a total of 30 g/m². It was tested against diaper backsheets used in competitive commercial diapers available under the trade names HUGGIES/ULTRATRIM, HUGGIES/SUPREME, PAMPERS/PREMIUM and DRYPERS/SUPREME.

All specimens were tested for hydrohead, MVTR, tensile strength (MD and CD) and percent elongation (MD and CD), and the data recorded in TABLE I.

The measurement of MVTR was accomplished by monitoring the amount of distilled water that evaporated through the specimen over a 24 hour period. The temperature of the water was maintained at 38° C. by using a constant temperature bath in which the jars of water were placed. A fan was used to maintain a constant air flow over the specimen. The height of the liquid was such that it did not interfere with the measurement as the top of the liquid was sufficiently above the bottom of the specimen.

The data of Table I shows that the hydrohead of a diaper backsheet made with the media according to the present invention (164) was second only to the Pamper/Premium (192), and that the MVTR and percent elongation thereof (MD and CD) according to the present invention (164) exceeded all others. The tensile strength (MD and CD) of the media composite according to the present invention were comparable to those of the competitive products.

The data illustrate that a backsheet incorporating the media of the present invention as the barrier layer is comparable, or superior, to competitive products in all pertinent respects and, in particular, is greatly superior with respect to MVTR. Indeed, the MVTR of a backsheet according to the present invention is at least twice as high as the MVTR of the backsheets of the commercial products tested.

Example II

Three specimens were prepared from identical polypropylene pellets useful in the present invention. The first specimen was processed according to the present invention, including quenching and compacting. The second specimen was processed in the same manner, except that the quenching step and the compacting step were omitted. The third specimen was similarly processed, but with the quenching step being included and only the compacting step being omitted. The fourth and fifth specimens were similarly processed, but with the compacting step being included and only the quenching step being omitted. The fourth specimen was compacted at 75 N and 100° C., while the fifth specimen was compacted at 150 N and 110° C.

Pertinent data was collected at various points in the processing as reported in TABLE II below.

As might be expected, the material of specimen 2, a common meltblown, exhibited an air permeability of about 193 cfm, higher than the 100 cfm upper limit of acceptability. Similarly, the material of specimen 5, quenched and compacted at a high temperature, was a rigid, brittle film exhibiting a low hydrohead of 8 mm H₂O, relative to the lower limit of 10 mm H₂O for acceptability. Specimens 3 and 4 exhibited relatively high air permeabilities (83 cfm for specimen 3 and 36 cfm for specimen 4) such that they were within the limit for media according to the present invention as broadly defined (0.1–100 cfm), but substantially higher than the preferred limit (0.4–3 cfm). Further specimen 4 exhibited an unacceptably low MVTR, while specimens 3 and 5 were so porous to moisture vapor as to be out of the range of the available MVTR tester used.

The data illustrate that the quenching step alone or the compacting step alone are insufficient to produce a preferred medium according to the present invention. A preferred medium according to the present invention results only when both the quenching step and the compacting step are both performed.

While both the quenching step and the compacting step are required to produce a preferred medium according to the present invention, the quenching step alone suffices to produce a media having a controlled pore size and a narrow pore size distribution. Indeed, such a media may combine high vapor permeability and low liquid permeability.

The colder the quenching air and/or the faster the quenching, the smaller the resulting pore size within the media, as the smaller crystals enable the larger crystals to fit closer together, with the resultant smaller pore sizes being formed by the combination of small and large crystals. In this connection, it will be appreciated that the smaller polymer crystals invade the large pores formed by the large polymer crystals so that the effective size of the pores is decreased—that is, there are more pores per unit volume due to the presence of the small polymer crystals as well as the large polymer crystals.

It will be appreciated that the unquenched and uncompact material exhibits large pores which may be of sufficient size to allow passage therethrough of both water and water vapor. On the other hand, when the material is quenched (even though not compacted), the material shrinks under the temperature differential (from extrusion temperature to quenching temperature) and the pores shrink in size, often enough to eliminate water passage therethrough and in extreme circumstances to limit the passage of water vapor (moisture) therethrough. Finally, when the material is both quenched and compacted, the pore size is further diminished so that the pores pass a limited amount of water vapor, but no water.

The pore sizes of the uncompact material may be measured by the permeability of the material, increasing permeability indicating increasing pore size and decreasing permeability indicating decreasing pore size. See TABLE III.

The products of the present invention find utility in the healthcare industry, as discussed previously, as well as such diverse fields as clean room and health care gowns, clean room filters, house wraps, sterile packaging, battery separators and other industrial applications with barrier requirements which can be met by the product of the present invention.

For those applications which require a more elastomeric and more drapable media, without any change in the barrier properties or other advantages of the present invention, the molten polymer from which the media of the present invention is preferably made from a blend of 60–90% polypropylene and 10–40% polybutylene by weight. Media made from such a blend exhibit a higher elongation to break and are much more drapable as compared to those made from 100% polypropylene. Since such media are more elastic and behave more like rubber, laminates using such media exhibit lower noise (that is, less crinkling). A preferred polybutylene for use in the present invention is available under the trade name PB DP 8910PC from Montell Chemical Co.

It will be appreciated by those skilled in the art that the hydrohead test is of a static nature and measures only the ability of the barrier media to withstand a water pressure gradually applied thereto; this is sufficient for many applications. However, certain applications require a more dynamic test to determine the capacity of the barrier media to withstand an impact suddenly driving the water there-against. The dynamic liquid impact test mimics the dynamic load/area (energy) that a baby will impart to a saturated core/backsheet structure when abruptly going from a standing to a sitting position. The dynamic liquid impact (in g/m²) is calculated based on the impact energy that an average 20 lb. baby will impart to a saturated diaper if the baby “falls” onto it from a standing position. The baby is modeled as two rigid links of known mass and length, and the assumption is made that the links “fall” from rest, with the impact area being the region under the diaper. This works out to be approximately 20 Joules (14.75 ft.-lb.) over an average baby “seat” area of 13.5 in.² or about 2300 J/m². Dynamic liquid impact was measured according to a proprietary Dynamic Liquid Impact Test Method V-L-35 of Proctor & Gamble.

A single layer of non-porous film alone gives a test result of 0 g/m². A single layer of laminate using a media according to the present invention gives a test result of 547 g/m². A sample of two layers of such laminate gives a test result of 375–465 g/m².

For a diaper backsheet, test results of less than 700 g/m², preferably less than 550 g/m², are acceptable on a 30 gsm laminate sample consisting of a spunbond layer (10 gsm), a central layer of media according to the present invention (10 gsm), and a meltblown layer (10 gsm) laminate.

Thus, the media of the present invention exhibits acceptable test results on a dynamic impact liquid test. The dynamic impact liquid test results confirm that the media of the present invention is the limiting factor.

A sample made of two laminates (for example, each laminate having the media of the present invention in the center, a spunbond on one side thereof, and a meltblown on the other side thereof) typically exhibits a lower dynamic impact liquid test level than a sample made of a single laminate alone. It is theorized that this is due to the increased

calendering of the media layers in the laminate affecting the morphology of the test material.

The materials of the present invention, as discussed hereinabove, may be even further improved through the use of the process modifications described hereinbelow. The first process modification enables embossing of a meltblown material, without the danger of tearing it, the meltblown material being part of a meltblown/spunbond sandwich. The second process modification enables the production of a compacted blend of materials including the compacted meltblown material, without the operational problems typically encountered in mixing a variety of polymers in a single hopper and without the resultant bottleneck in the production line. The third process enables perforation of the meltblown material so that it is useful as a cover or top sheet characterized by a high strikethrough of bodily fluids and a low level of rewetting. Each process modification will be described separately hereinbelow.

Typically, meltblown materials are not embossed or patterned (especially when used in oil absorption, sound absorption or thermal insulation applications) because the meltblown material is by itself too delicate for the embossing operation, and any attempt to emboss or pattern it will result in pinholes (and possibly larger holes) being formed therein. By way of contrast, spunbond materials are stronger (because the filaments are already bonded together by passage through a set of rolls) and may even be used as a carrier to support a meltblown material.

Referring now to FIG. 3, it has now been found that in the first process modification a sandwich, generally designated **100**, of the compacted meltblown material **102** of the present invention and a spunbond material **104** may be embossed in such a way as to prevent hole formation in the meltblown material during the embossing operation. As the sandwich **100** passes through the embossing station, generally designated **106**, the meltblown material **102** (with its lower melting point) softens before the spunbond material **104** (with its higher melting point). This occurs, even though the spunbond material **104** is preferably adjacent the heated hard roll **108** of the lamination station **106** and the meltblown material **102** is preferably adjacent the unheated soft roll **110**.

In order to enhance the visual appearance and/or tactile feel of the meltblown media **102** of the present invention, a textile or non-woven material (preferably a spunbond **104**) is laid onto the traveling compacted meltblown material **102**. The sandwich **100** of the compacted meltblown material **102** and the added spunbond material **104** is then optionally passed over a preheating roll (not shown) which brings the two materials closer to the lamination temperature. Thereafter, the sandwich **100** of the two materials **102**, **104** is passed through a lamination station **106** which uses heat and/or pressure to impose a pattern on the materials. The lamination station **106** typically includes a heated hard roll **108** (typically formed of steel) and a non-heated soft roll **110** (typically formed of a material softer than steel, such as nylon, rubber, or the like). Preferably the heated hard roll **108** is disposed adjacent the spunbond material **104** passing through the lamination station **106**, while the non-heated soft roll **110** is disposed adjacent the meltblown material **102**. The heated hard roll **108** of the lamination station **106** impresses a pattern of depressions **112** on the hot meltblown layer **102** (through the spunbond layer **104**), with a mating pattern of projections on the hot meltblown layer **102** being formed where the heated hard roll **108** does not form depressions **112**. The pattern is formed most clearly in the meltblown layer **102** which softens under the heat and

pressure applied thereto and, if at all, less clearly in the spunbond layer **104**. In the context of the present invention, in order to maintain the MVTR high, care must be taken to ensure that the temperature and pressure applied do not result in conversion of the meltblown layer **102** into an impermeable film.

The embossing serves at least two functions: first, to bond the spunbond/meltblown or spunbond/meltblown/spunbond layers **104/102** or **104/102/104** together into a laminate, generally designated **116**, and prevent delamination thereof (which may be done with or without any patterning being imposed upon the materials passing therethrough), and, second, to impose an embossing pattern on the meltblown layer. Preferably the meltblown material **102** is of relatively small fiber size (relative to the spunbond material **104**) so that it is substantially uniform and therefore uniformly accepting of the embossing. At least one of the heated spunbond materials **104** generally enters into the depressions formed in the meltblown **102** by embossing of the sandwich **100** passing through the laminating station **106**. Thus, the pores of the meltblown **102** are filled in the laminating station by the heat-softened fibers of the spunbond **104**.

The resulting sandwich material or embossed laminate **116** is aesthetically appealing (because of the patterns which may have been impressed thereon), resists delamination, and is thicker than any of the components by themselves. The laminate retains desirable barrier properties (e.g., a high MVTR) and, where desired, may have an enhanced strength (e.g., a strength suitable for envelopes). The meltblown and spunbond materials together contribute additional strength to the laminate.

Generally, the bonded portions of the meltblown and spunbond materials of the laminate **116** appear translucent, while the non-bonded portions appear opaque or white.

Pertinent parameters of the laminating or compacting station **138** include the temperature and pressure exerted on the laminate, the speed of the laminate, and the percentage bonding area of the laminate.

For backsheet applications relying on desirable barrier properties (e.g., a high MVTR), line pressures of 50–300 Newtons per millimeter (preferably 75), roll temperatures of 25–200° C. (preferably 100–128° C.) and speeds of 20–200 meters per minute (preferably 150) are preferred for laminates of about a 20 gsm (grams per square meter) compacted meltblown and about a 17 gsm spunbond, whether the same are made exclusively of polypropylene or polyester. As the basis weights increase, the speed should be lowered to compensate for the heat transfer effect by the sample at a given line pressure. It is also possible to run the laminate at a higher speed by using higher line pressure or having a greater embossing depth for heavier fabrics. The percentage bonding area for the compacted fabric after lamination is preferably about 5–50%, lower percentage bonding areas being useful for back sheets (for example, 20% or less) and higher percentage bonding areas (for example, 20% or more) being useful for front sheets and the like.

For making a Tyvek-type laminate of polypropylene, polyethylene terephthalate, polyethylene and their blends, generally the same operating conditions may be used albeit with both the hard roll and the soft roll being smooth—that is, without an embossing pattern. The same temperature and speed ranges are used, but the pressure range is 50–600 Newton per millimeter (preferably 300).

Referring now to FIG. 4, in order to enable the compacted media **102** of the present invention to be economically formed of a polymer blend (as opposed to, say, 100% main

polymer, here polypropylene **130**), in the second process modification at least one addition station **132** is disposed intermediate the station **136** where the meltblown is formed and quenched and the station **138** where it is compacted—i.e., intermediate the quenching station **136** and the compacting station **138**. A hopper disposed at each addition station **132** releases heated (but unmelted) addition material **140** intended to be blended with the main polymer (here, polypropylene **130**) from the quenching station **136**. The subsequent compaction step at the compaction station **138** causes the addition material **140** to bond and become integrated with the main polymer **130**.

Preferred addition materials for use in the addition stations include polymers such as polyethylene, polyurethane and ethyl vinyl alcohol, these specific materials being preferred for their ability to contribute softness and elasticity to polypropylene. The addition material **138** released by the hopper of the addition station **132** may be in the form of a powder, paste, particulates, or staple fibers (the latter preferably being less than 4 denier). Also useful as addition materials for use in the addition stations **132** are fibers of a different diameter than the fibers leaving the quenching station **136**. A plurality of different addition materials may be added at each addition station, if desired. Thus a second addition material **140** may be added to the main polymer/first addition material **130/140** at a second addition station **132**.

The use of the addition stations **132** avoids the need to separately process addition materials such as polyethylene and polyurethane, which are well recognized in the art as being difficult to employ in a production setting. A further advantage is that the use of separate addition stations **132** avoids the formation of the production line bottleneck which would otherwise occur if all of the addition materials **140** had to be blended with the main polymer **130** in a single hopper, a rather time-consuming operation. Furthermore, blending in a single hopper of the meltblown material **130** and any addition materials **140** could occur only if the meltblown material **130** and the addition materials **140** are miscible and have appropriately similar melting points.

It will be appreciated that the quenching step provides additional strength to the meltblown material **130** at an early stage, so that it is thereafter capable of receiving and supporting the addition materials **140**. If it is desired to utilize the resultant material for its barrier property (e.g., high MVTR), the meltblown material **130** must undergo compacting. The addition material **140** added before compacting becomes incorporated into (and embedded within) the meltblown material **130**, but typically it is not melted completely.

A fibrous material, such as a meltblown, useful as a cover or top sheet for fluid transport to an absorbent core, must be characterized by a high strikethrough of bodily fluids (which may be of different consistency and viscosity—e.g., urine, blood) from the body side to the absorbent core and preferably by less rewetting from the side of the absorbent core. The high strikethrough and typically lower rewetting is preferably accomplished by increasing and shaping the pore size in the direction of the desired liquid flow.

Referring now to FIG. 5A, in one preferred embodiment of the third process modification, the present invention both increases the pore size (to increase strikethrough) and shapes the pores (to reduce rewetting). This is achieved through post-compaction hot needle perforation, whereby the fibers of the compacted meltblown material **102** become plasticized after perforation with the pointed tip **160** of a hot

needle to form a tapered perforation **162** and, after withdrawal of the needle point **160**, the plasticized fibers freeze to stabilize the shape of the convergently tapered perforation **162** heading to the absorbent core. Optimally, hot needle perforation is performed asynchronously at two perforation stations so that the perforations formed by one station do not repeat, and preferably do not even overlap, the perforations performed at the other station. The process melts the open area of the perforations with holes of different hole shapes and diameters, preferably interfering with subsequent capillary action leading to rewetting. The compacted fibrous layer may preferably have a density of 10–25 gsm, according to the needles used.

Referring now to FIG. 5B, in another preferred embodiment of the third process modification, the suction box **54** used to draw the uncompacted molten polymer filaments **56** from the quenching station **136** may utilize a perforated rotating screen **170** and a high vacuum (suction) air stream **172**. The suction causes the heated filaments to be sucked through the convergent screen perforations **174**, thereby to form a pattern of three-dimensional trumpet-like or convergent perforations **162** in the uncompacted material.

In either case, a micro-relief surface is created which does not feel spongy or filmy, does not hold liquid and reduces resetting. The fibrous layer has small pores or perforations, which pass only low viscosity fluids and is soft to the feel and configuration. Because of the configuration of the perforations **162** formed, especially by a hot pointed needle penetrating the fibrous layer, rewetting is minimized. (By way of contrast, perforation of a film does not preclude, or even minimize, rewetting.)

Compaction is not necessarily required, but preferably the perforation should take place after compaction in order to keep the fibrous layer as thin and drapable as possible. The compaction prevents the fibrous layer from absorbing parts of the body fluid into itself (the latter causing a wet feeling after multiple flushes of body fluids).

Thus, the present invention provides a soft, smooth, drapable fibrous perforated layer of high fiber density, low porosity (and therefore breathable), and high abrasion resistance, the layer being characterized by accurately formed perforations (no matter how formed) and being especially useful for disposable diapers and various feminine hygiene products.

The materials of the present invention find utility in a wide variety of industrial applications. For example, the materials are useful as filters for air filtration, car filters, liquid filters and filter bags. The materials are also useful in industrial protective clothing such as clean room apparel, commodity consumer clothing, dust protection and chemical protection. The materials are further useful as industrial wipes such as clean room wipes, oil absorption wipes, lens cleaning wipes, and surface protection for low friction and/or non-scratch surfaces. Other industrial applications for the materials include house wrapping, packaging, furniture and bedding, car covers, insulation, battery separators, shoe components and the like.

Further, the materials of the present invention find utility in a wide variety of hygiene applications. For example, the materials are useful as top sheets, backsheets or outer covers, leg cuffs, waistbands, stretch tabs, elastic or extendable side panels, and acquisition or distribution layers.

Finally, the materials of the present invention also find utility in a wide variety of medical applications. For example, the materials are useful as surgical drapes, surgical gowns, cut-in-place gowns, shoe covers, bouffant caps and sterilization wrapping.

The specification of particular applications hereinabove is to be taken as exemplary only, and not as limiting. Uses other than the aforementioned industrial, hygiene and medical applications follow naturally from the physical and chemical properties of the materials of the present invention.

The controlled porosity fabrics of the present invention are generally useful in each of the aforementioned industrial applications, hygiene applications and medical applications.

To summarize, the present invention provides a method of making a media of controlled porosity, preferably a media combining high vapor permeability and low liquid permeability, which method does not require a specialized polymeric input or the use of chemical binders, additives or coatings to provide the desired permeability. The present invention also provides material made by the aforesaid method, such material not producing noise during use, exhibiting cloth-like feel (hand), and being sufficiently economical to manufacture for use in disposable products.

While the general thrust of the invention as described hereinabove has been directed to a fibrous media combining high vapor permeability and low liquid permeability, it should be appreciated that where high vapor permeability is not a critical factor (although low liquid permeability remains a critical factor), materials may be made according to the process of the present invention which exhibit low liquid permeability and little, if any, vapor permeability. Indeed, it is theorized that a full range of moisture vapor transmission rates (MVTR) from about 100 to about 13,000 g/m²/24 hrs may be formed according to the method of the present invention.

The low vapor transmission rates are obtained by closing the pores defined by the fibers prior to compaction. Thus the use of a high compaction temperature and/or a high compaction pressure can close the pores of the fabric sufficiently to produce a fabric exhibiting a relatively low moisture vapor transmission rate (typically less than 1,000 g/m²/24 hrs). It is believed that the elevated compacting parameters melt the fibers which then shrink, thereby closing the pores. Whether the closing of the pores is achieved through the use of a higher compaction temperature or a higher compaction pressure will depend upon the ultimate application of the fabric being produced. The use of a higher compaction temperature tends to produce a more rigid fabric, while the use of a higher compaction pressure tends to produce a fabric retaining its original softness.

By way of example, a preferred smectic polypropylene melt-blown fabric is calendered at a roll surface temperature of up to 145° C. (relative to the 25° C.–110° C. temperature used to produce a high moisture vapor transmission rate fabric), a roll surface pressure of up to 300 Newtons (rather than the 25–150 Newtons used to produce a high moisture vapor transmission rate fabric), at a roll speed of up to 200 meters per minute. Roll surface temperatures over about 110° C. results in a softening of at least a proportion of the large polymer crystals, while roll surface pressures of 300 Newton results in deformation of all sized polymer crystals within the fabric. If the temperature and/or pressure of the calender are too high (or the roll speed too low), then the over-calendered melt-blown fabric is converted from a high moisture vapor transmission rate fabric into a film which is totally impermeable to both gas and liquid (so that it has a very low moisture vapor transmission rate) and typically of low strength and low tear resistance.

It will be appreciated that the porosity control achieved by the present invention is obtained by a mechanism clearly distinguishable from the mechanism used in the prior art.

The prior art teaches the deployment of particulates—e.g., calcium carbonate (CaCO₃)—in a film and creates the porosity either by stretching the film to open the pores around the particulates or by removing the particulates from the film, thus leaving voids which provide the porosity. By way of contrast, the fabrics of the present invention are fibrous networks having several advantages relative to the prior art films. In particular, they are purer (since they are not contaminated by any residue of the particulates used to obtain porosity), lighter (about 10 gsm v. 30 gsm for the prior art films, since there is no particulate residue), and cheaper (since no particulates are used therein and the process adapts itself to existing plant equipment for fiber formation). They enable precise control of the moisture vapor transmission rate (through control of the compacting temperature and compacting pressure). Additionally, they exhibit a higher tear strength (as evidenced by tensile, trapezoid tear and Elmendorf tear tests) and a higher resistance to compaction or burst test strength (since the basic structure remains as a fibrous network within the formed compacted media). For any or all of the above reasons, materials according to the present invention may be preferred over the prior art materials even where the moisture vapor transmission rate is not a concern. Where the moisture vapor transmission rate is not a concern, obviously the number of possible applications for the fabrics is greatly increased. The absence of particulates, or the residue of removed particulates, in the fabric renders the material especially well suited for hygiene applications.

Accordingly, the present invention further encompasses a method of making a fibrous media combining controlled vapor permeability and low liquid permeability wherein the fabric (as described above) is calendered or compacted to soften substantially all of the small polymer crystals therein having low heats of fusion and a controlled proportion of the relatively larger polymer crystals therein having relatively higher heats of fusion, thereby to control vapor permeability while providing low liquid permeability. As described above, appropriate adjustments of the compacting temperature and/or compacting pressure can provide a fabric of low liquid permeability and controlled vapor permeability (whether high or low), without the temporary introduction and subsequent removal of particulates from the fabric (as in the prior art).

While the low moisture vapor transmission rate material of the present invention may be used by itself, typically it will be laminated with a layer of spunbond for particular applications, such as use as a diaper backsheet.

The material of the present invention is particularly well-suited for a novel application requiring high tensile strength and high tear resistance as well as essentially no liquid permeability and a relatively high vapor permeability. Accordingly, the material is useful as a barrier insulator for a home or building during its construction. (Once a plywood house/building is framed, the plywood is wrapped in a barrier insulator before the exterior surface (e.g., shingles) is applied.) The material must be quite strong (i.e., exhibit high tensile strength and tear resistance) and waterproof (i.e., exhibit essentially no liquid permeability), while remaining vapor breathable to enable the escape of moisture vapor and the like.

An insulative barrier fabric is produced under the trademark TYVEK (available from DuPont). This product is made from 100% high density flashspun polyethylene fibers bonded together by heat and pressure. The TYVEK material is also used in sterile packaging, high strength envelopes, protective or barrier clothing, and the like.

21

A competitive material of the present invention is a multi-layer (as illustrated, a three-layer) SCS fabric. The intermediate or "C" layer is the basic compacted fibrous media of high vapor permeability and low liquid permeability made by premature crystallization and then calendaring or compacting as described hereinabove. This "C" layer is then sandwiched between two outer or "S" layers of spunbond fabric, and the three layer "SCS" construction is then passed between two rolls for cold lamination.

In cold lamination, one roll is a smooth soft roll and the other roll is a smooth hard roll. For example, the smooth hard roll may be formed of steel while the smooth soft roll may be formed of RACOLON, a type of nylon (available from KTM, Germany). In order to achieve cold lamination, the surface temperature of the rolls is preferably maintained no higher than 100° C. (and preferably 25° C.-90° C.) and the surface pressure of the rolls is maintained relatively high, at 270-800 Newtons/mm (preferably 500 N/min).

Referring now to TABLE IV, therein indicated are the properties of a sample according to the present invention and two different types of TYVEK (one having a slightly lower basis weight and one having a slightly higher basis weight than the sample). The "C" layer of the sample is a compacted meltblown layer of 10 gsm made from polypropylene resin (available from Montel) having a melt flow index (MFI) of 1000. The two "S" layers of the sample are EXXON 3825 polypropylene resin (available from Exxon), one having a basis weight of 34 gsm and the other having a basis weight of 20 gsm. The three layers were laminated together at 100° C. and 500 N/mm pressure between smooth steel and soft RACOLON calender rolls at 15 m/min.

As it will be appreciated from the data, the fabric according to the present invention has a very high strength (see MD tensile, elongation to break, and Young's modulus data) and a very high tear resistance (see trapezoid tear data). Additionally, it has a relatively high hydrohead of 118 in. H₂O and a high moisture vapor transmission rate of 2632 g/m²/24 hrs. The spunbond or "S" layers are quite permeable to both liquid and vapor, but provide the laminate with the high strength required for a TYVEK-like product. Thus the high MVTR and hydrohead arise almost exclusively from the meltblown or "C" layer, which controls the passage of liquid and vapor through the laminate. In other words, the barrier properties of the TYVEK-like product are produced by the compacted meltblown layer according to the present invention.

Now that the preferred embodiments of the present invention have been shown and described in detail, various

22

modifications and improvements thereon will become readily apparent to those skilled in the art. Accordingly, the spirit and scope of the present invention is to be construed broadly and limited only by the appended claims, and not by the foregoing specification.

TABLE I

	Huggies/ Ultratrim	Huggies/ Supreme	Pampers/ Premium	Drypers/ Supreme	FQF
Hydrohead (mbar)	110	72	192	69	164
MVTR g/m ² / 24 hrs	1495.5	1944.1	1198.4	1046.8	4411
MD Tensile (N)	53.14	46.32	71.18	47.6	80.23
CD Tensile (N)	19.98	45.15	17.52	23.07	43.23
MD Elong %	30.4	53.6	107.13	52	40.85
CD Elong %	40.36	30.11	132.18	54.37	62.92

TABLE II

Specimen	Hydrohead mbar	MVTR g/m ² @ 24 hr	Air Permeability cfm
1	59 ^A	4187	0.5
2	29 ^A	—	193
3	40 ^A	—	83
4	70 ^C	1148	36
5	8 ^C	—	1

Legend =

^ATest head size 28 cm²

^BTest head size 38 cm²

^CTest head size 5 cm²

TABLE III

Units	Hydrohead mbar	Air Permeability cfm	CD Tensile N	CD Elongation %	CD Modulus Mpa	MD Tensile N	MD Elongation %	MD Modulus Mpa
Test Head Size	28 cm ²	38 cm ²						
Sample 1*	39.5	82.88	7.24	64.64	11.35	12.41	33.63	37.06
Sample 2*	28.5	193	3.95	65.18	5.20	6.87	40.18	15.86

*Average of four specimens. Test head size for hydrohead is 28 cm², and test head size for air permeability is 38 cm².

TABLE IV

Properties	Test Method	Sample	S-1059B	TYVEK S-1073B	
Basis wt. (Oz/yd ²)	* D751	2	1.9	2.2	5
MD Tensile (lbs/in)	* D751	49.49	35.4	41.7	
Elong. to Break (%)	* D751	40	18.10	20.20	
Young's Modulus (Newtons)	* D751	545	?	?	10
Hydrohead (in.H ₂ O)	160.0/89	118	59	62	
MVTR (g/m ² /24 hrs)	* E-96	2632	?	?	
Trapezoid Tear (MD in Newtons)	* D1117	96	?	?	15

* ASTM

** EDANA

We claim:

1. A method of making a laminate including a non-woven fibrous media combining high vapor permeability and low liquid permeability, the method comprising the steps of:

(A) providing a non-woven meltblown fabric formed of fibers that have small polymer crystals therein of low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion, the fibers being formed of a polymer drawn and then prematurely crystallized by premature quenching with a stream of cold quench air immediately after drawing prior to completion of fiber formation to form both small polymer crystals therein of low heats of fusion and relatively larger polymer crystals therein of relatively higher heats of fusion, and then collected during fiber collection to form the fabric;

(B) calendering the fabric at a roll surface temperature of 25–110° C., a nip linear force of about 25–150

Newtons/mm, and a roll speed of up to about 200 meters/minute, the temperature, pressure and roll speed of the calendering operation being cooperatively selected to soften the small polymer crystals therein of low heats of fusion, but not the relatively larger polymer crystals therein of relatively higher heats of fusion, thereby to retain a high vapor permeability, of at least about 1200 g/m² @24 h, while providing a low liquid permeability as measured by a hydrohead of at least about 10 millibars, through compaction, fiber shrinkage and contraction in the fibrous media;

(C) forming a laminate of the calendered fabric and a second material; and

(D) passing the laminate through an embossing station to impose a pattern of depressions and projections on the calendered fabric whereby the second material enters the depressions of the embossed calendered fabric.

2. The method of claim 1 wherein the second material is at least one woven textile layer.

3. The method of claim 2 wherein the woven textile layer is formed of synthetic fibers.

4. The method of claim 1 wherein the second material is cellulosic fibers.

5. The method of claim 4 wherein the cellulosic fibers are formed at least in part of paper pulp.

6. The method of claim 1 wherein the second material is a nonwoven formed of synthetic fibers.

7. The method of claim 1 wherein the second material is a nonwoven formed of cellulosic fibers.

8. The method of claim 7 wherein the cellulosic fibers are formed at least in part of paper pulp.

9. The method of claim 1 wherein the second material is a high strength spunbond on each side of the calendered fabric.

* * * * *



US005497789A

United States Patent [19][11] **Patent Number:** **5,497,789****Zook**[45] **Date of Patent:** **Mar. 12, 1996**[54] **FOOT PROTECTOR INCORPORATING A VISCOELASTIC GEL**[76] Inventor: **Gerald P. Zook**, 760 E. 29th Ave., Eugene, Oreg. 97405[21] Appl. No.: **969,530**[22] Filed: **Oct. 30, 1992****Related U.S. Application Data**

[63] Continuation of Ser. No. 453,150, Dec. 20, 1989, abandoned, which is a continuation-in-part of Ser. No. 273,710, Nov. 17, 1988, abandoned, which is a continuation-in-part of Ser. No. 75,425, Jul. 20, 1987, abandoned.

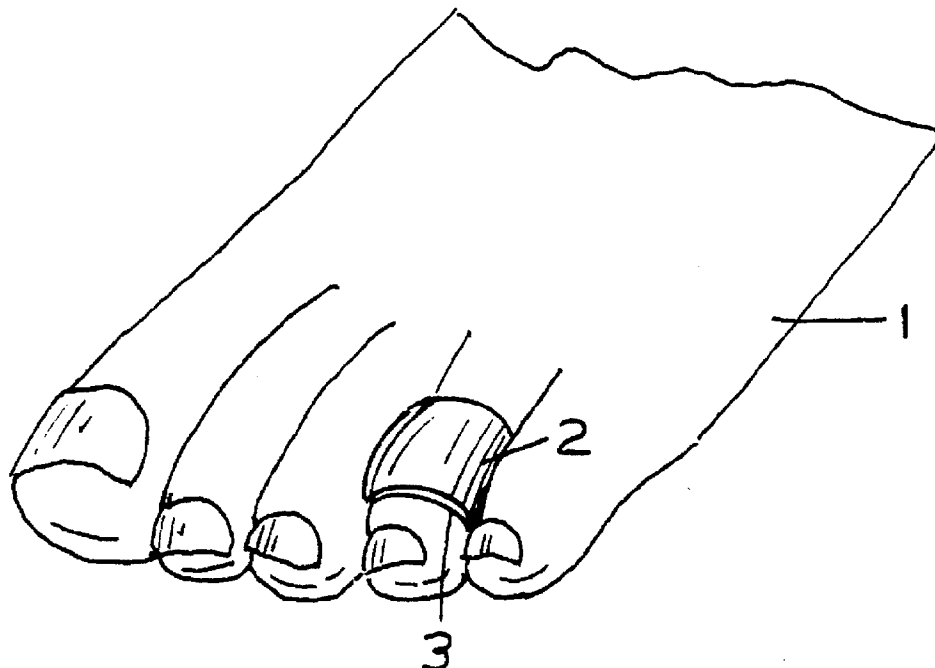
[51] Int. Cl.⁶ **A61F 13/06**[52] U.S. Cl. **128/893; 128/894**[58] Field of Search **128/893, 112, 128/113, 117, 593, 894; 602/41**[56] **References Cited****U.S. PATENT DOCUMENTS**

Re. 13,608	8/1913	Rightmire	128/893
21,790	10/1858	Wheat	128/894
281,487	7/1883	Georges	128/894
707,089	8/1902	Duckworth	128/153
2,044,523	6/1936	Bertram	128/153
2,115,237	4/1938	Scholl	128/893
2,585,691	2/1952	Scholl	128/153
2,646,795	7/1953	Scholl	128/153
2,740,401	4/1956	Crawford	128/153
2,781,044	2/1957	Bennett	128/153
2,827,049	3/1958	Scholl	128/153
2,943,623	7/1960	Thompson	128/153

3,209,750	10/1965	Levitt	128/153
3,229,690	1/1966	Scholl	128/153
3,253,591	5/1966	Scholl	128/894
3,487,832	1/1970	Spence	128/153
3,547,120	12/1970	Grossman	128/153
3,548,420	12/1970	Spence	3/20
3,968,530	7/1976	Dyson	5/449 X
4,369,284	1/1983	Chen	524/476
4,380,569	4/1983	Shaw	428/283
4,414,964	11/1983	Farino et al.	128/153
4,456,642	6/1984	Burgdorfer et al.	5/449 X
4,516,571	5/1985	Buchan	128/893
4,699,146	10/1987	Sieuerding	128/640
4,756,949	7/1988	Spence et al.	428/68 X
4,842,931	6/1989	Zook	428/354

Primary Examiner—Michael A. Brown[57] **ABSTRACT**

A padding and medicating device for corns, hammertoes, bunions, blisters, and the like comprising a noncompressible, thermoplastic, oleaginous, viscoelastic gel directly impregnated onto a carrier structure of elastic fabric. The ultrasoft gel is retained on and compressed against the body part being treated by the elastic tension of the fabric which causes the noncompressible gel to expand radially outward, flow over the lesion, and conform to the shape of the lesion in a manner which dissipates externally-applied pressure equally throughout the fabric-gel-tissue system. The invention also internally absorbs frictional or horizontal shearing forces, delivers a therapeutically significant dose of a lubricating, soothing, and emolifying oil such as Mineral Oil U.S.P., and is further capable of delivering a pharmacologically active substance to the foot lesion.

16 Claims, 2 Drawing Sheets

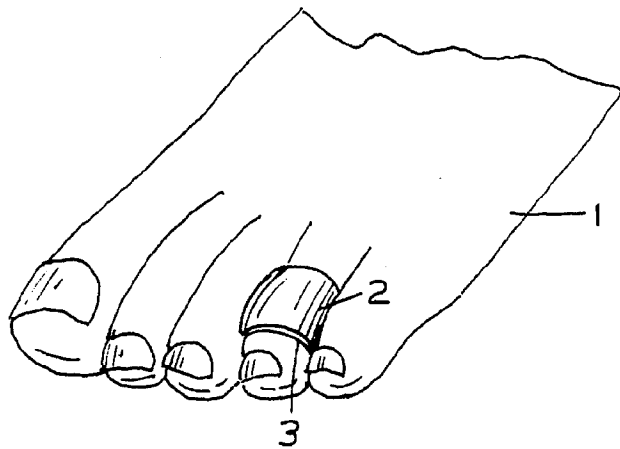


FIG. 1

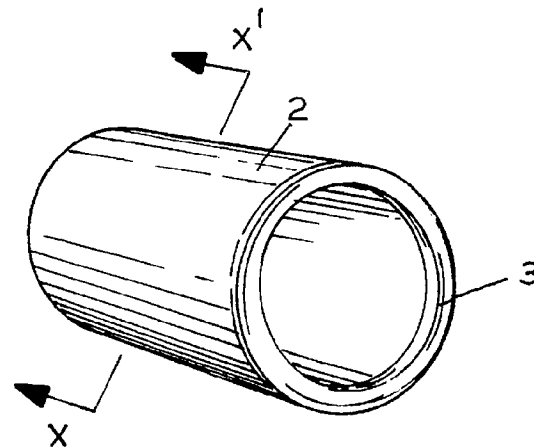


FIG. 2

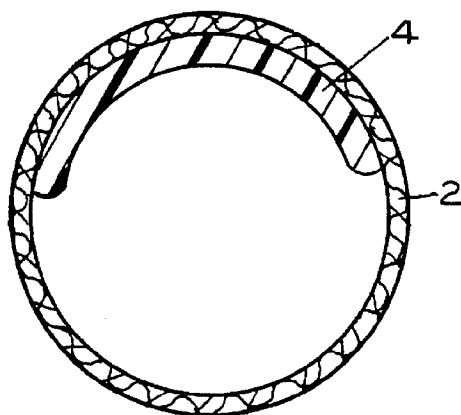


FIG. 3

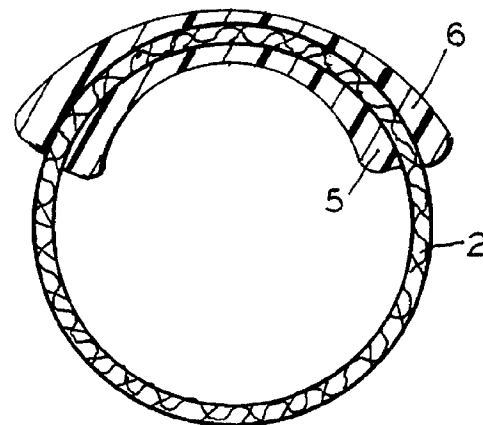
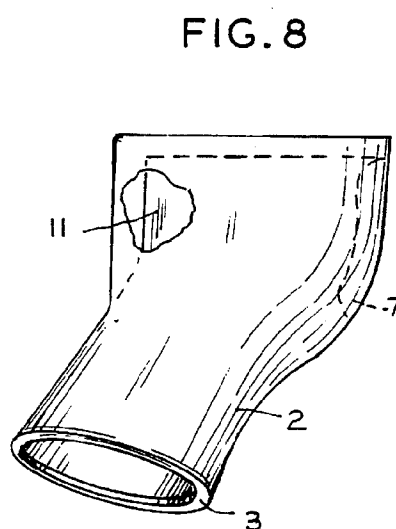
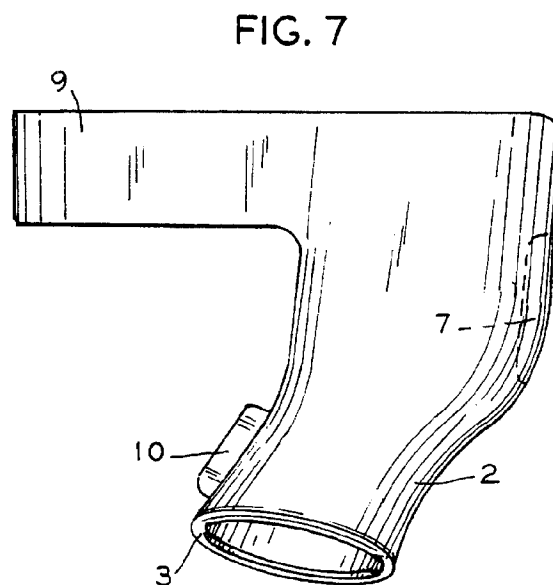
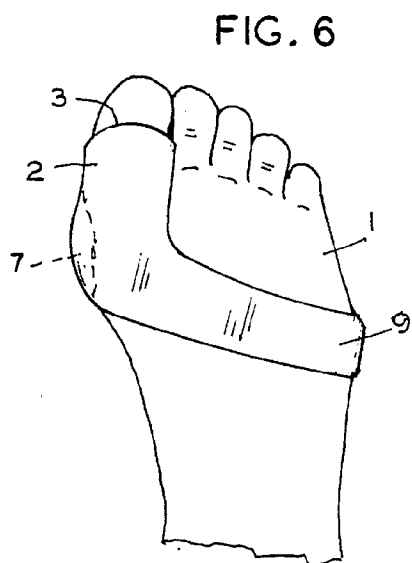
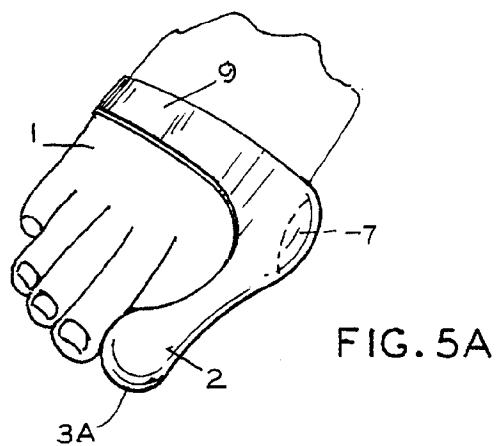
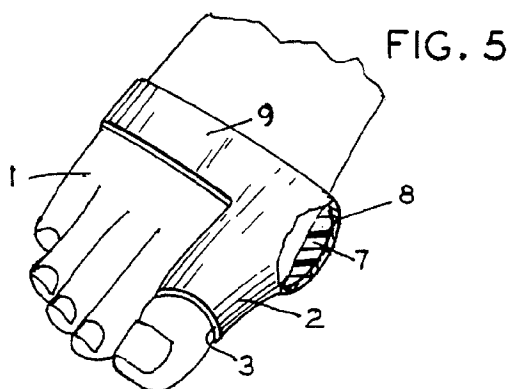


FIG. 4



FOOT PROTECTOR INCORPORATING A VISCOELASTIC GEL

REFERENCE TO RELATED APPLICATIONS

This application is a continuation of 07/453,150 filed Dec. 20, 1989, now abandoned, which is a continuation-in-part of Application Ser. No. 273,710 filed Nov. 17, 1988, now abandoned, which is a continuation-in-part of Application Ser. No. 075,425 filed Jul. 20, 1987, now abandoned.

BACKGROUND—FIELD OF INVENTION

This invention relates to foot pads, more specifically to foot pads incorporating a viscoelastic gel with superior friction and pressure-dissipating characteristics as well as medicinal properties.

BACKGROUND—DESCRIPTION OF PRIOR ART

The art of foot padding and medicating devices is old and crowded. Historically, pads for corns, hammertoes, bunions and the like have been manufactured from compressible materials such as felt or foamed latex. This trend continues today as evidenced by the large numbers of such products available on the over-the-counter foot care market.

Wheat in U.S. Pat. No. 21,790 describes a corn eradicator comprising an elastic band and a pad or cushion. Wheat does not disclose what his pad is made of, but most pads of that era were made of fabric such as felt or even softened leather. Wheat shows a relatively narrow elastic band holding the device in place. One disadvantage of a narrow elastic band is that it concentrates pressure on the plantar digital arteries as it loops around the toe. Georges in U.S. Pat. No. 281,487 describes a corn or bunion shield made of discs of soft leather or fabric and a central area of oiled silk to relieve friction. Georges' invention suffers from the following objections: the leather and flannel discs will become compressed and lose their cushioning ability with use, the oiled silk used to relieve friction can leave an oil stain on socks or shoes, the digit encircling elastic band is relatively narrow and thus may impede blood flow in the plantar digital arteries, and the device is not washable and therefore could become unhygienic. Duckworth in U.S. Pat. No. 707,089 teaches a corn pad having an internal cavity to relieve pressure on a corn or bunion and a digit encircling elastic strap. Duckworth's internal cavity would be difficult to manufacture and merely concentrates pressure on the soft tissue surrounding the corn. Again, his narrow elastic band would create pressure on the plantar digital arteries. Schultz in U.S. Pat. No. 893,876 describes a foot protector made of multiple layers of felt or other compressible fabric that may be adjusted by removing one or more layers. Compressible materials such as wool or felt will eventually "bottom out" and lose their ability to cushion. These materials are also poor dissipaters of frictional forces and do nothing to soften and lubricate a keratotic lesion. Patent No. 13,608 to Rightmire teaches a medicating device for cutaneous lesions consisting of one or more medicinal cups affixed to a digit by an elastic tubular carrying structure. The cups are rigid and would create painful pressure points adjacent to the flange structure around the lesion. This device would be of no value in dissipating frictional forces generated by shoe gear. U.S. Pat. No. 2,057,72 to Koppe teaches a corn pad of felt or the like secured to a digit by means of an adhesive strip. This device would not be removable and the felt pad would not be able to absorb frictional forces like a viscoelas-

tic gel would. Scholl in U.S. Pat. No. 2,115,237 teaches a medicated button made of an adhesive plastic mass and incorporating medication. Since the button is made of an adhesive material, it cannot readily be removed and reapplied. Since the plastic mass is composed of relatively stiff materials, it will not dissipate shearing forces as a viscoelastic gel would. U.S. Pat. No. 2,015,497 to Scholl describes a two-component corn plaster with a medicated disc covered with a pressure-relieving corn pad. This device is not removable and reusable and is not made of materials that would dissipate pressure and friction in the "hydraulic" manner as the elastic gel of the present invention. Crawford in U.S. Pat. No. 2,784,401 teaches a foot-corrective pad made of foamed latex with a central aperture to relieve pressure and a covering of rubber or the like. As with many other prior art references, the foamed latex of Crawford's invention is compressible and when subjected to shoe pressure will become a dense, unyielding material with poor pressure or sheer dissipating properties. A viscoelastic gel, on the other hand, is noncompressible and is capable of dissipating friction and pressure even when subjected to extreme shoe pressure. This fact can be readily demonstrated by taking a corn pad of the present invention, applying firm, or even extreme pressure to the gel pad with a finger, and rubbing to and fro. The finger in this instance will glide almost effortlessly to and fro as the frictional forces are dissipated internally by the gel. The gel will also conform to the contour of the digit to more evenly spread out the pressure exerted upon it from a direction perpendicular to its major surface. This last point means that an aperture, such as described by Crawford, is not a critical feature when utilizing an elastic gel, an important manufacturing consideration. Levitt in U.S. Pat. No. 3,209,750 teaches a digit-embracing surgical pad made of foamed latex which suffers from the same objections as the device taught by Crawford. U.S. Pat. No. 3,244,171 to Neu teaches a surgical pad with a digital loop. This bunion shield is made of compressible materials such as felt or foam rubber and has a large central aperture to relieve pressure and friction. Again, these materials are poorly adapted to dissipate pressure and friction and will bottom out with time. Thompson in U.S. Pat. No. 2,943,623 teaches a skin plaster made of tetrafluoroethylene which has a very low coefficient of friction. This device does nothing to pad or soften the keratotic lesion as described in the present invention.

Gelatinous materials are well known to the art of orthopedic cushioning devices. Spence in U.S. Pat. No. 3,548,420 teaches a cushion made with an organosiloxane gel covered by a layer or layers of cloth, foamed plastic or the like. This device has the disadvantage of incorporating a gel without the ability to impart Mineral Oil U.S.P. to a keratotic lesion to soften and lubricate the lesion. Furthermore, the gel in Spence's invention is not elastic enough to dissipate frictional forces when applied in extremely thin layers as described below for the present invention. The same objections hold true for Spence's U.S. Pat. Nos. 3,308,491 and 3,663,973 which teach similar organosiloxane gel devices. Shaw in U.S. Pat. No. 4,380,569 teaches lightweight pre-formed stable gel structures that incorporate glass micro-spheres. Again, these devices do not bleed Mineral Oil U.S.P. onto a keratotic lesion and lack the elasticity to dissipate friction from shoe gear when employed in extremely thin layers. Burgdorfer et al., in U.S. Pat. No. 4,456,642, teaches gel pads with the same objections as Spence and Shaw.

OBJECTS AND ADVANTAGES

Accordingly, several objects and advantages of my invention are:

- (a) To provide a novel pad for corns, calluses, bunions, blisters, and the like which is able to equalize pressure when applied over an uneven surface, such as found with many foot disorders, by utilizing an ultrasoft viscoelastic noncompressible gel which is capable of conforming to the shape of the lesion when pressure is applied and dissipating this pressure in a "hydraulic" manner which spreads this pressure more equally over a larger area than any prior inventions known to this art.
- (b) To provide a foot protective and cushioning device which is able to internally absorb frictional or horizontal shearing forces encountered as the foot slides forward and backward inside the shoe during the walking cycle when employed in thinner layers than heretofore known in this art.
- (c) To provide a pedal cushioning device which is extremely simple in its design, manufacture, and use. In its simplest form, the present invention is made of only two components, a carrier structure of elastic fabric and a pad of viscoelastic gel which has been impregnated thereupon.
- (d) To provide a pad capable of delivering a therapeutically significant amount of skin softening and lubricating oil such as Mineral Oil U.S.P. or a medicinal agent such as keratolytic agent, antifungal, or antibacterial agent, vesicant, or any other pharmacological agent that would be beneficial to the user.
- (e) To provide a safe digital cushioning device that is secured to the digit by means of a broad elastic tube rather than a narrow elastic band so that this elastic force is distributed over a wide area so as not to impede circulation to the digit.
- (f) To provide a pad for corns, hammertoes, bunions, and the like which is easy to apply and remove, is hand or machine washable, is reusable, and is reversible.
- (g) To provide a digital padding device with a tubular elastic fabric member which resists fraying without the necessity of employing time-consuming, expensive, and awkward antifraying measures by using a seamless elastic tubular material which will spontaneously roll inward at the ends of the pad to form a cuff.

Further objects and advantages of my invention will become apparent from a consideration of drawings and ensuing descriptions of the same.

BRIEF DESCRIPTIONS OF THE DRAWINGS

FIG. 1 is a perspective view of a corn pad of the present invention positioned on the fourth toe of a foot.

FIG. 2 is a perspective view of a corn pad of the present invention illustrating the elastic tube structure and the rim or cuff of the tube.

FIG. 3 is a sectional view of the corn pad pictured in FIG. 2 taken at line X—X¹ and illustrating a viscoelastic gel of uniform thickness impregnated on the interior of the elastic sleeve.

FIG. 4 is a sectional view of a corn pad of the present invention illustrating gel pads of variable thickness positioned on both the interior and exterior surfaces of the elastic tube.

FIG. 5 is a perspective view of a bunion pad of the present invention positioned on a foot with the aid of a metatarsal encircling strap.

FIG. 5A is a variation on the bunion pad illustrated in FIG. 5, but with the distal aspect of the elastic tube structure closed.

FIG. 6 is a plantar view of the bunion pad of the present invention illustrated in FIG. 5, affixed to a foot.

FIG. 7 is a perspective view of a bunion pad of the present invention with a metatarsal encircling elastic band and a viscoelastic gel pad positioned on the lateral external surface of the digital sleeve.

FIG. 8 is a perspective view of a bunion pad of the present invention without a metatarsal encircling band.

DESCRIPTION OF THE INVENTION

FIGS. 1–4 illustrate one preferred embodiment of the present invention which in its simplest form comprises only two components, a sleeve of elastic fabric 2 and a pad(s) of viscoelastic gel 4, 5, 6 impregnated thereupon. FIG. 1 illustrates a corn pad of the present invention that has been applied to a toe. The elastic sleeve 2 encircles the digit and holds the viscoelastic gel in direct contact with the corn or other lesion. FIG. 2 illustrates the elastic sleeve 2 of a corn pad of the present invention and shows the cuff 3 formed around the rim of sleeve 2 by the inward rolling of the elastic fabric. FIG. 3 is a cross-sectional view of the embodiment of the present invention shown in FIG. 2 to illustrate the location of a layer of uniform thickness of viscoelastic gel 2, specifically on the interior aspect of the elastic sleeve 2. This configuration allows for the oleaginous gel 4 to come into direct contact with the corn or other lesion to facilitate softening and lubrication of the corn with the plasticizing oil of the gel. This configuration also enhances the gel's ability to freely conform to an uneven surface without hindrance from a sheet of material that might be used to cover the gel. In FIG. 3, the layer of viscoelastic gel is of essentially uniform thickness. FIG. 4 illustrates one embodiment of the present invention wherein the layers of gel 5, 6 have a variable thickness. In FIG. 4 the surface of the gel 5 intended for contact with the skin is depicted as a concave in shape to better adapt to the convexity of a corn or hammertoe, for example. The gel pad or pads of the corn pad thus may be of uniform thickness, variable thickness, or even zero thickness where an aperture is desirable.

The manufacture of the present invention as illustrated in FIGS. 1–4 is extremely simple. My technique involves purchasing a commercially available tubular sleeve of elastic fabric; flattening this elastic fabric on a level surface such as a workbench; laying circular molds on the fabric; and pouring heated, liquefied polymer directly into the mold and allowing it to cool and re-gel. For my prototypes, I have been using a seamless tube of elastic fabric from ½" to 2" in diameter available from Surgical Appliance Industries of Cincinnati, Ohio. The advantage that I have found with this particular knit is that it resists fraying around the rims by spontaneously rolling up at the rims to form a cuff 3 (FIG. 2) at either end as described in greater detail subsequently in this disclosure. After flattening this elastic fabric tube on a level working surface, I place the gel molds directly on the surface of the fabric where the gel is to be deposited. For gel molds I have been using rubber washers of varying diameters and thicknesses. Such rubber washers are readily available at most hardware or plumbing stores. These washers are simply laid on the fabric with no need to secure them in the desired position. Next, I take some commercially available viscoelastic gel such as the thermoplastic gelatinous composition taught by Chen in U.S. Pat. No. 4,369,184 and sold under the name of Glue-Balls® by Hymen Products and heat these in a saucepan on an electric stove. Once the gel has been heated to around 350° F. and converted to a free-flowing liquid, I simply pour a small portion of the liquefied polymer into the mold and allow it to cool and re-gel. Once the hot, liquefied gel is in the mold, it begins to

5

penetrate the elastic fabric and is partially absorbed by the fabric. Upon cooling and re-jelling of the polymer, the viscoelastic gel becomes intimately bonded to the fabric. After the polymer has cooled and re-jelled, the molds are simply lifted off of the fabric and the impregnation of the fabric with the gel is complete. The next step involves simply cutting the fabric between consecutive gel pads, dusting the gel with talc, and turning the short tube segments inside out so that the gel pad resides on the interior aspect of the finished device. When using the above-mentioned tubular knit manufactured by Surgical Appliance Industries, no elaborate means such as applying an antifraying substance to the cut edges of the elastic fabric are required to achieve a reusable, washable, and reversible device that will not fray at the ends. Another advantage of this extremely simple method of manufacture is that no costly injection molding procedure or equipment is required. In order to obtain a gel pad of variable thickness, as illustrated in FIGS. 4 and 5, several simple steps can be employed. The method I prefer involves pouring the liquefied gel into the mold and letting it cool to approximately its gelling temperature. At this point, the gel is still moldable, somewhat like putty. I take a rubber ball coated with talc and press it down on the exposed surface of the gel. This "stamps" the gel into the desired shape. Obviously, modifications of this basic concept could be made to facilitate mass production. Another technique I have employed to achieve a varied thickness to the gel involves laying a small object such as a coin under the fabric to be coated with gel such that the fabric becomes elevated and reduces the distance between the surface of the fabric and the top surface of the mold.

FIGS. 5-8 illustrate a bunion pad of the present invention. FIG. 5 depicts one embodiment of the invention wherein a digit encircling elastic tube 2 is applied to the hallux to anchor the distal aspect of the bunion pad. As with the corn pad depicted in FIG. 3, the distal rim of the device is a cuff 3 (FIGS. 5-8) formed by the inward rolling of the elastic fabric sleeve 2. Alternatively, as illustrated in FIG. 5A, the distal end of elastic tube 2 may be closed 3A. In this case the elastic fabric tube forms a "sling" that fits over the distal aspect of the digit to anchor the device against proximal migration. The proximal medial segment of the bunion pad 8 is made of elastic fabric which covers the dorsal aspect of the first metatarsophalangeal joint, wraps around the medial aspect of the joint, and covers the plantar aspect of the first metatarsophalangeal joint as illustrated in FIGS. 5 and 6. A metatarsal encircling elastic strap 9 (FIGS. 5-7) connects with the proximal dorsal aspect of the proximal segment 8 of the bunion pad, courses dorsally over the metatarsus of the foot 1, wraps around the fifth metatarsal proximal to the metatarsal head, courses across the plantar metatarsus, and connects with the plantar proximal-lateral aspect of the proximal aspect 8 of the bunion pad. A pad of viscoelastic gel 7 is impregnated on the interior aspect of the device in a location corresponding to the roedial aspect of the first metatarsophalangeal joint. Gel pad 7 may be of uniform thickness, variable thickness, or even zero thickness when an aperture is desired. One embodiment of the invention employs a gel pad with a central concave depression to interface with the convexity of a bunion. Referring to FIG. 7, an optional gel pad 10 may be impregnated onto the external lateral surface of the hallux encircling segment 2 of the device. Pad 10 functions as a toe spacer between the first and second digits. Pad 10 could just as well be impregnated onto the interior surface of sleeve 2. Referring to FIG. 8, an alternative embodiment of a bunion pad of the present invention is illustrated. Structures 2, 3, and 7 are substan-

6

tially as described for the embodiment depicted in FIGS. 5-7. The primary difference between the bunion pad illustrated in FIG. 8 and the bunion pads illustrated in FIGS. 5-7 is that the bunion pad in FIG. 8 lacks the metatarsal encircling elastic strap 9. The elastic fabric may be reinforced with a rigid or semi-rigid backing structure in this embodiment so that gel pad 7 is retained in its most advantageous position relative to the bunion. The plantar proximal aspect 11 of the device is indicated by the dotted line in FIG. 8.

My method for manufacturing the bunion pad of the present invention is as follows. Beginning with an approximately 3-inch segment of elastic tubular fabric (Surgical Appliance Industries, Cincinnati, Ohio) a pad of viscoelastic gel is impregnated on one surface using the same technique as described above for the corn pad of the present invention. This pad is substantially in the center of the longitudinal axis of the elastic sleeve. After the gel has cooled, the sleeve of elastic fabric is inverted such that the gel pad is on the interior surface of the elastic sleeve. Using ordinary scissors, a cut is made longitudinally for approximately three-fourths the length of the elastic sleeve on the opposite side of the sleeve as the viscoelastic gel. The resultant device is now substantially the same as the embodiment pictured in FIG. 8. Next, a segment of elastic strap material approximately 4-6 inches long is sewn onto the device at the proximal aspects of the elastic tubular material where the longitudinal cut was begun. One end of the elastic strap is sewn to the dorsal proximal aspect of the device and the other end of the elastic strap is sewn onto the plantar proximal aspect of the device. This results in the bunion pad illustrated in FIGS. 5 and 6. An optional gel pad may be impregnated onto either the exterior or interior surface of the bunion pad at the distal aspect as illustrated by 10 (FIG. 7). This substantially results in the finished product ready for use.

OPERATION OF THE INVENTION

The corn pad of the present invention is practiced by simply slipping the elastic tubular member over the digit. The viscoelastic gel pad can be positioned by rotating the elastic fabric and by pulling the elastic fabric carrier structure proximally or distally on the digit. Since the elastic fabric will naturally apply slight pressure on the extremely deformable viscoelastic gel in the direction of the digit, the gel will spontaneously assume the surface configuration of the lesion being treated, thus eliminating the need to modify the shape of the pad during manufacture. Since this viscoelastic gel behaves like a fluid when pressure is applied, this pressure will be more equally dissipated throughout the gel in a "hydraulic" manner similar to the way pressure is dissipated through the braking system of an automobile when pressure is applied to the brake pedal. In response to the pressure, the ultraconformable, noncompressible, viscoelastic gel will "flow" over the surface being treated and fill in voids in the surface so as to equalize pressure over the surface being treated in a manner far superior to conventionally-used materials such as compressible felt or foam rubber. When pressure is applied to the noncompressible viscoelastic gel, it will "flatten out" by expanding its radius or surface area. Thus, the applied pressure will be spread out over a greater area with less pressure per unit of area.

When frictional or horizontal shearing forces are applied to the invention, this force is internally absorbed by the gel without the gel pad sliding forward and backward on the digit. These results cannot be duplicated in prior inventions known to the art of pads for corns, calluses, bunions, blisters,

and the like, because of the unique properties of the gel of the present invention. Gels heretofore known to the art of orthopedic padding devices have such limited elasticity and such poor tearing parameters that they will usually split into two or more pieces when stretched to about twice their resting length. This inability to elongate to many times its original length thus impedes the ability of these gels to flow in response to pressure or frictional forces. When using a gel such as described by Chen in U.S. Pat. No. 4,369,284 in the present invention, new and unexpected results are discovered. The most significant of these results from a clinical standpoint is the tremendous amount of frictional or shearing forces that can be absorbed by a relatively thin layer of such a gel. The aforementioned gel of Chen is capable of being stretched to 1600% of its original length before tearing. For the sake of illustration, one can imagine a pad of the present invention with a 2.0 mm thick pad of such a material. When a shearing force is applied parallel to a major surface of this hypothetical 2.0 mm gel pad, this surface is displaced laterally while the elastic gel stretches. A 2.0 mm thick pad of such a material could thus be displaced 2.0 mm $\times 16$, or nearly 32 mm (1 and $\frac{1}{4}$ inch) in one direction. By reversing this shearing force 180°, the gel will return to its resting point and then begin stretching in the opposite direction an equal distance. The total range of motion in this hypothetical case would thus be 1.25 inches $\times 2$ or 2.5 inches. One can see in this example the superior friction dissipating ability that one can realize when using a thin layer of such a material—an important consideration in the narrow confines of a shoe. The above discussion is presented to better illustrate the direct relationship between gel elasticity and shear dissipating ability. In real-life situations the results may vary. Nonetheless, it seems reasonable that if one particular gel pad was capable of being elongated four times as much as a second gel pad, the first gel pad could absorb approximately the same amount of shearing force as the second gel pad when the first gel pad is only one-fourth the thickness of the second gel pad. This economy of space is submitted to be a significant breakthrough when compared to the prior art. Therefore, for the purposes of the present invention, only viscoelastic gels capable of elongating to at least 200% of their original length without tearing are considered as compatible with the present invention.

An analogous argument can be constructed to illustrate the superior pressure dissipating ability of such gels in the present invention. In the case of force applied perpendicular to the major surface of a gel of the present invention, such pressure is dissipated by the flow of the gel radially outward from an area of higher pressure to an area of lower pressure. Likewise, it seems reasonable in this case that a gel that can easily elongate to many times its original resting length would do a better job of dissipating pressure in an hydraulic manner.

When the invention is applied over the dry, compacted keratin in a corn, for example, plasticizing oil such as Mineral Oil U.S.P. will be transferred from the gel to the keratotic lesion to soften and lubricate the lesion. Medications incorporated into the gel will likewise be delivered to this superficial lesion.

When utilizing an elastic fabric tube made from material such as described above, no expensive, time-consuming, or elaborate measures to prevent fraying of the fabric are required because the cut edges of the elastic tube will spontaneously roll up to form a fray-proof "cuff."

When the corn pad of the present invention becomes soiled, it can simply be removed and machine-washed and dried. I have subjected prototypes of the invention to several

cycles of washing and drying without any noticeable change in their ability to function as described above. When desirable, the elastic fabric sleeve can be turned inside out so that the gel resides on the external surface of the tube. In one embodiment of the invention, gel pads are deposited on both surfaces of the elastic tube opposite each other. With this device, one can position the pads between two adjacent toes to function as a toe spacer that will help realign the digits. This is an important function for people suffering from hallux abductovalgus or bunion formation where the great toe deviates away from the midline of the body and presses into the adjacent toes.

The operation of the bunion pad of the present invention is similar to that of the corn pad. To apply the bunion pad illustrated in FIG. 8, the distal tubular member 2 is simply slipped over the digit so that the gel pad 7 is positioned over the medial aspect of the first metatarsophalangeal joint (or over the lateral aspect of the fifth metatarsophalangeal joint in the case of a tailor's bunion). When applying the embodiment of the bunion pad illustrated in FIGS. 5-7, the elastic strap 9 is first pulled over the metatarsus of the foot. Next the digit (either hallux or little toe) is slipped into the distal tubular aspect 2 of the device. This device positions the gel pad over or around a bunion where it can gently apply lateral pressure to realign a splayed first or fifth metatarsal. The proximal pull of elastic fabric is transmitted to the digit encircling sleeve in such a manner as to realign a deviated metatarsophalangeal joint.

To better understand the operation of the present invention, the following discussion of the more salient features of the present invention is submitted. My invention is fundamentally different from the prior art because it takes advantage of the unique properties of a noncompressible, relatively fluid, highly conformable, viscoelastic gel to overcome the inability of previously described pads to dissipate localized points of pressure created against the foot when wearing shoes. In the parent applications, I describe this ability of certain viscoelastic polymers to flow around an uneven surface when pressure is applied in such a manner as to equalize the pressure throughout the area as "hydraulic" in nature and similar to the way in which "hydraulic fluid distributes pressure equally in all directions in a pump or brake device." When ultrasoft, highly conformable, noncompressible viscoelastic gels are used according to the method taught in this patent application, this is precisely the case. The materials that I have been working with are exemplified by the thermoplastic elastomer gelatinous compositions taught by Chen in U.S. Pat. No. 4,369,284. If one were to take a cylinder 3" in diameter and $\frac{1}{2}$ " in height, for example, and made of felt, foam rubber, or any of the other materials described in this art and were to step on it with a bare foot, what would happen is that these compressible materials would decrease in volume and increase in density. In those areas where pressure from the foot were greatest, the material would be the densest and least able to cushion. This compacted material would also lose its limited ability to absorb horizontal shearing of frictional forces such as found when walking with a shoe on. Such a pad would not appreciably expand or spread outwardly in a radial manner in such a way as to increase the surface area of contact between the foot and the pad and thus dissipate the force over a larger area. When a noncompressible viscoelastic gel of the same dimensions is utilized in place of the compressible padding material, the results are quite different. As force is exerted downward on the ultrasoft, highly deformable, noncompressible gel, it instantly begins to flow radially outward in a manner which greatly increases the surface area

of contact between the gel and the foot. This increased surface area dissipates the weight over a larger area, resulting in a lower pressure per unit of area. This force tending to spread out the gel is opposed by the intrinsic elastic properties of the viscoelastic gel, and this spreading will cease when these two forces are in equilibrium. Likewise, there will be no discrete pressure points found within the gel due to the unequal pressure applied by the irregularly-shaped foot. In those areas where pressure would build up in the conventional pad, the gel will flow radially outward and dissipate this pressure throughout the system in a "hydraulic" manner which is far superior to the way that pressure is dissipated in a noncompressible material. Unlike materials heretofore used in this art, a viscoelastic gel will not lose its ability to internally absorb frictional or horizontal shearing forces when subjected to pressure. In fact, the ability of these types of gels to internally absorb these horizontal shearing forces when subjected to pressure is so great as to render them unsuitable for use as insoles unless incorporated into a system that restricts this tendency to slide horizontally. This is an important consideration when discussing pads for corns, bunions, and especially blisters because much of the pain and inflammation resulting from these conditions is the result of friction between the foot and the shoe that is generated during walking as the foot slides forward and backward inside the shoe.

There are several difficult and subtle problems that must be recognized and solved when incorporating a highly deformable, ultrasoft, noncompressible, viscoelastic gel into a pad for corns, hammertoes, bunions, and the like. The first problem relates to the tendency for gels to migrate away from an area of increased pressure, especially when this is an intermittent pressure such as found inside a shoe when walking. This repeated pumping action would cause an unsecured gel to be squeezed away from the area of high pressure to an area of lower pressure. The present invention solves this problem by directly impregnating a thermoplastic viscoelastic gel onto fabric. This is accomplished by heating the gel to a temperature that converts it to a free-flowing liquid. This hot liquid is then poured onto a fabric and allowed to cool and re-gel. While in the heated-liquid state, the viscoelastic polymer will penetrate the fabric, be partially absorbed by it, and bond to the fabric when it cools and returns to the gel state. This impregnation process serves to bond the gel to the fabric so that the fabric can prevent the gel from excessive migration when pressure is applied. Even though the gel may be highly stretchable, it will not be able to travel far when the gel is applied in a layer less than 1.0 cm thick. Thus, the fabric "tethers" the gel to prevent unlimited migration. The second problem encountered when devising a pad for corns, hammertoes, and the like using a viscoelastic gel is related to the above first said problem and is actually the converse of it. Ideally, one would like to create a system that prevents excessive and unlimited migration of the gel but, at the same time, facilitates the limited type of gel migration required to maximize the equilibration of pressure throughout the gel. One would also want to avoid a gel-fabric system that would allow a portion of the gel to be squeezed out of the pad where it can become entangled in the sock. These objectives are best satisfied by utilizing a two-way stretchable elastic fabric such as Spandex®. Since such a fabric is itself elastic, it will stretch a limited amount with the gel in response to an increase in localized pressure to facilitate the dissipation of this pressure and better equalize the pressure in the gel-fabric system. As the gel expands radially outward in response to pressure, so too does the fabric. Thus, the viscoelastic gel and the elastic fabric work

synergistically to equalize the dissipated pressure over a larger area of the foot. This also prevents the gel from being squeezed out of a cleft between the fabric and the skin which could cause the gel to be pulled away from the pad when socks are applied or removed because of the sliding frictional force applied to the gel as the sock is pulled on or off. This is one problem I have encountered utilizing viscoelastic gel with nonelastic fabrics. A third and related problem encountered when utilizing viscoelastic gels in this art is their floppy nature and tendency to roll up into an amorphous ball of gel in response to horizontal frictional forces such as encountered when putting on a sock or walking in a shoe. For this reason, it is important that the entire surface of the gel be either in contact with the skin or covered with a sheet of fabric that secures the entire mass of the gel to the body part being treated by applying force in the direction of said body part. This is why I have chosen the elastic tube structure for this invention which is intended for use on a human digit which is cylindrical in shape. The relationship between the elastic fabric and the viscoelastic gel is very similar to the relationship between skin and fat in the mammal. Skin essentially is a two-way stretch elastic covering for subcutaneous fat which pads in a manner exactly the same as the viscoelastic gel of the present invention. The elastic fabric tube will apply even compression to the entire surface of the gel that is not in contact with the skin and thus eliminate any unsecured extension of the gel which would roll up in response to friction such as found when applying a sock.

Thus, the reader will see that the present invention is a highly-useful and novel device for padding and medicating corns, calluses, bunions, blisters, hammertoes, and the like. The invention dissipates the pressure and friction exerted upon the foot by a shoe when walking in a manner far superior to any device known to this art. The present invention is further capable of lubricating, softening, moisturizing, and medicating foot lesions in a manner heretofore not known to the art. The present invention is an orthopedic padding device that self-conforms to the shape of a foot lesion without the need to preshape the gel pad during manufacture; internally absorbs horizontal shearing or frictional forces; is easy to apply and remove; dissipates the elastic compressive forces utilized to hold it in place over a larger surface area so as not to interfere with circulation to the digit; and is machine washable, reversible, and reusable.

While the above description contains many specificities, these should not be construed as limitations on the scope of the invention, but rather as an exemplification of several preferred embodiments thereof. For example, materials which do not match the specific definition of a "gel" but which have equivalent physical properties such as a highly deformable, ultrasoft, noncompressible, viscoelastic rubbery material such as may be formulated using silicone or other such materials could be substituted into the present invention. Likewise, materials with similar physical properties which are not thermoplastic could be utilized to achieve the same results as the gel in the present invention. For example, a multipart chemical material which "sets up" or cures after mixing could be impregnated onto the elastic tubular means of the present invention with equivalent results. Also, a physically similar compound that cures upon exposure to air or heat could be utilized in the present invention. Furthermore, it is to be understood that this device is as easily adapted to treat a fifth metatarsophalangeal (or tailor's) bunion as it is the hallux abductovalgus-type bunion.

I claim:

1. A padding device for the human foot, comprising:

11

- a. a tubular sleeve of elastic fabric fitting about a digit and having an inside surface, an outside surface and opposing ends;
 - b. said tubular sleeve of elastic fabric being formed of a seamless tubular material which spontaneously rolls inwards about each end of said tubular sleeve to form a cuff thereat; and
 - c. a pad of viscoelastic gel;
 - d. said pad of viscoelastic gel being directly impregnated onto said inside surface of said tubular sleeve of elastic fabric.
2. The padding device, as recited in claim 1, where the viscoelastic gel includes plasticizing oil in the form of Mineral Oil U.S.P.
3. The padding device, as recited in claim 2, where the plasticizing oil is perfused with an oil soluble medicinal agent.
4. The padding device, as recited in claim 1, wherein said pad of viscoelastic gel is capable of being stretched at least 200 percent of any resting dimension without tearing.
5. The padding device, as recited in claim 1, wherein the viscoelastic gel is thermoplastic in nature.
6. The padding device, as recited in claim 1, wherein, additionally, there is a second pad of viscoelastic gel which is impregnated directly upon the outside surface of said tubular sleeve.
7. The padding device, as recited in claim 1, wherein the pad of viscoelastic gel is of uniform thickness.
8. The padding device, as recited in claim 1, wherein the pad of viscoelastic gel varies in thickness.
9. A padding device for the human foot, comprising:
- a. an elastic fabric member having a portion in the form of a tubular sleeve to encircle a digit of the human foot and a non-tubular portion which extends from said digit encircling tubular sleeve to lie adjacent to a metatarsophalangeal joint associated with said digit;
 - b. said tubular sleeve portion of said elastic fabric member being closed at the distal end so as to encompass the distal end of said digit to prevent migration of the padding device; and

12

- c. a pad of viscoelastic gel;
 - d. said pad of viscoelastic gel being directly impregnated onto said non-tubular portion of said elastic fabric member so as to be positioned adjacent to said metatarsophalangeal joint.
10. The padding device, as recited in claim 9 above, wherein, additionally, an elongated strap of elastic fabric is attached to said non-tubular portion of said elastic fabric member, said elongated strap of elastic fabric being formed to encircle the metatarsal region of the human foot.
11. The padding device, as recited in claim 9 above, where said pad of viscolastic gel varies in thickness.
12. The padding device, as recited in claim 9, wherein said viscoelastic gel includes Mineral Oil U.S.P. as a plasticizer.
13. The padding device, as recited in claim 12, wherein said plasticizer includes an oil soluble medicinal agent.
14. The padding device, as recited in claim 9, wherein said viscoelastic gel is thermoplastic.
15. The padding device, as recited in claim 9, wherein said pad of viscoelastic gel is capable of being stretched at least 200 percent of any resting dimension without tearing.
16. A padding device for the human foot, comprising:
- a. an elastic fabric member having a portion in the form of a tubular sleeve to encircle a digit of the human foot and a non-tubular portion which extends from said digit encircling tubular sleeve to lie adjacent to a metatarsophalangeal joint associated with said digit; said tubular sleeve having an inside surface and an outside surface;
 - b. a first pad of viscoelastic gel being directly impregnated onto said non-tubular portion of said elastic fabric member so as to be positioned adjacent to said metatarsophalangeal joint; and
 - c. a second pad of viscoelastic gel which is directly impregnated upon said outside surface of said tubular sleeve encircling said digit so as to lie between, and separate, said digit and a second, adjacent digit.

* * * * *